AMERICAN COLLEGE of CARDIOLOGY

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September 12, 2025

The Honorable Mehmet Oz, MD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1832-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Medicare and Medicaid Programs; CY 2026 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; and Medicare Prescription Drug Inflation Rebate Program

Submitted via www.regulations.gov

Dear Administrator Oz:

The American College of Cardiology (ACC) appreciates the opportunity to provide comments on the Centers for Medicare & Medicaid Services (CMS) on the CY2026 Physician Fee Schedule and Other Changes to Part B Payment policies proposed rule. The College's comments focus on the proposed efficiency adjustment, changes to indirect practice expense methodology, telehealth policy, new code valuations or re-valuations, Software as a Service, the Ambulatory Specialty Model (ASM), the Quality Payment Program (QPP) and the continued integration of interoperable health information technology, and other miscellaneous topics.

The American College of Cardiology (ACC) is a global leader dedicated to transforming cardiovascular care and improving heart health for all. For more than 75 years, the ACC has empowered a community of over 60,000 cardiovascular professionals across more than 140 countries with cutting-edge education and advocacy, rigorous professional credentials, and trusted clinical guidance. From its world-class JACC Journals and NCDR registries to its Accreditation Services, global network of Chapters and Sections, and CardioSmart patient initiatives, the College is committed to creating a world where science, knowledge and innovation optimize patient care and outcomes. Learn more at *www.ACC.org* or connect on social media at @ACCinTouch.

Conversion Factor

CMS proposes two separate conversion factors (CFs) for the CY2026 PFS. The first would apply to practitioners participating in an Advanced Alternative Payment Model (AAPM) at $33.59. The second would apply to practitioners not participating in an AAPM at $33.42. AAPM practitioners

are proposed to receive a 0.75% increase in their CF while non-participants' increase would be 0.25%. The CF was also increased 2.5% per statutory requirement for CY2026 only. Further, the CF received a 0.55% increase from a positive budget neutrality adjustment due to the proposed efficiency adjustment.

While the CF adjustment appears to be approximately a 3.83% increase for AAPM participants and a 3.33% increase for non-participants, the reality is far less positive. The proposed efficiency adjustment would reduce essentially all non-E/M or behavioral health services by 2.5%. Further, the proposed shifts in indirect practice expense calculations would reduce many services by an additional 7% or more.

The ACC appreciates and supports the positive statutory increases to the CF outside of those derived by the efficiency adjustment. However, the College urges CMS to acknowledge and consider that these increases are completely nullified and then some for large portions of the medical professional community due to other policies within this proposed rule.

Adjusting RVUs To Match the PE Share of the Medicare Economic Index (MEI)

Current regulations utilize the MEI to determine the relative weights of work, practice expense (PE) and malpractice (MP) in the fee schedule. Total relative value units (RVUs) in the PFS are proportioned to approximately 51 percent work RVUs, 45 percent PE RVUs, and 4 percent MP RVUs. In CY 2023 rulemaking, CMS finalized a plan to rebase and revise the MEI to reflect more current market conditions based on 2017 MEI data, but delayed implementation, in part, to potentially incorporate practice cost data being collected by the American Medical Association (AMA) from physician practices that could be used to derive cost share weights for the MEI and RVU shares.

Rather than implement PE per-hour or cost shares from the AMA's survey data, CMS proposes to continue using current PE per-hour and 2006-based MEI cost shares for 2026. The ACC believes that the newly available AMA survey data is the most current and accurate on which CMS could act. CMS discusses implementing prior changes during a four-year transition, and that could certainly be done here. **The ACC recommends CMS implement new MEI shares of work, PE and PLI RVUs from the AMA data, which results in the following distribution: work = 54.4%; PE = 43.8 percent; and PLI = 1.7%.**

Refreshed Data and Request for Information on Timing to Effectuate Routine Practice Expense Updates

In recent rulemaking, CMS has continued to seek feedback and suggestions for evidence that could shape optimal PE data collection and methodological adjustments over time. Significant deference was given to the pending execution of a Physician Practice Information Survey (PPIS) by the AMA in deferring updates to PE data and methodology. The PPIS was completed in 2024 and data shared

with CMS in early 2025 with the intent to inform future CMS actions regarding PE per hour data and cost shares in PFS rate setting for 2026.

In this proposed rule, CMS opts not to make updates based on the recent PPIS. CMS cites concerns regarding accuracy, utility, and suitability of the PPIS as an immediate replacement for the current PE/HR data and cost shares for use in allocating nearly $91 billion in payments across PFS services. CMS also itemizes limitations that include low response rates and representativeness of the survey data, small sampling sizes and sampling variability, lack of comparability to previous survey data, potential measurement error, and missing/incomplete data submission. Because of these concerns, no changes are proposed to the current PE per hour data or cost shares for 2026, whether informed by the PPIS or RAND Corporation contracted efforts.

The AMA, with the support of the ACC and scores of medical societies, undertook this significant effort to meet CMS data needs. **The ACC urges CMS to work with the medical societies to better understand and address concerns with the PPIS data, and/or find ways to augment it so it could be utilized in future rulemaking instead of the site of service payment differential (discussed below) that it does propose.** As an instructive point of history, the ACC expressed great concern about the accuracy of the 2007/2008 PPIS data for cardiology. Many of the same concerns the agency cites against the recent survey were leveled at the cardiology data in the 2007/2008 PPIS, yet CMS proceeded to use that data to implement updates that produced significant and disruptive payment cuts to cardiology services. To mitigate disruption, the resulting payment changes were phased in over four years. To be consistent with that approach, the ACC would also support CMS making such a change now—adopt new PE/hr data from the recent PPIS, phase it in over four years, and continue to make enhancements as appropriate.

Potentially Misvalued Services Under the PFS

Remote interrogation device evaluation

An interested party nominated CPT code 93296 *(Interrogation device evaluation(s) (remote), up to 90 days; single, dual, or multiple lead pacemaker system, leadless pacemaker system, or implantable defibrillator system, remote data acquisition(s), receipt of transmissions and technician review, technical support and distribution of results)* as potentially misvalued. The current inputs were reviewed by the RUC in 2016 and essentially affirmed the inputs from the code's creation for 2009. The ACC has previously found it difficult to assess the inputs for remote interrogation services of this nature and recognizes there could be shortcomings. For instance, it is unlikely that a single clinical staff member will follow a single patient through the entire 90-day period and can precisely account for their time for various activities during the course of the 3 months and could track all activities for a single patient during that span.

Eighty percent of remote interrogation services are billed by clinicians directly, with about 20% billed by independent diagnostic testing facilities (IDTFs). Some portion of the 80% billed by clinicians is likely performed by IDTFs and billed as a purchased service. In researching the topic to inform this comment, member experts agreed there are elements that should be updated to reflect the evolution of technology and workflows during the intervening years since last review. Cardiac

implantable electronic device (CIED) remote monitoring and management is complex and requires significant staff time, experience, and expertise. This work is heterogeneous depending on the practice location and setting. Daily work includes patient enrollment, data review, alert triage, communication with patients and physicians, documentation, and other tasks. These personnel require advanced training/oversight. Devices now have numerous alerts, battery advisories, and disconnections, which means the frequency of device checks and management have increased. Patients are eager to hear promptly from the office.

The guidance offered in a recent expert consensus document from the Heart Rhythm Society and others explains clinic staffing, appropriate clinic workflows, patient education, alert management, and other topics.[1] That document adequately summarizes the work in a modern CIED clinic and shows significant evolution from the current inputs. Staff with more training perform more tasks for these services than in 2009 or when inputs were essentially affirmed in 2016. It remains the case that long duration, remote interrogation services are difficult to assess. Supplies, equipment, and clinical staff type could be updated with a good degree of confidence. Estimation of clinical staff time is much more challenging. One or several staff follow the remote interrogation data over the 90 day-period performing various tasks, making it difficult to accurately estimate time. One could divide the staff member's total time worked across the number of patients managed to get one answer. ACC has had success in a different instance in obtaining logs from vendors that support recommendations for minutes per reporting period. Finally, one could do a survey, as was done with this nomination. **All of which is to say that the materials accompanying the potentially misvalued nomination may be the most accurate information available on the topic. One solution CMS could apply is to adopt the information from the nomination as updated inputs for the fee schedule in the final rule.**

Efficiency Adjustment

CMS proposes to apply an efficiency adjustment to the vast majority of codes in the physician fee schedule. The proposal outlines various concerns the agency has with the process by which the RUC initially establishes and subsequently updates code values. The agency raises concerns over the accuracy of the RUC recommendations due to low survey response rates, low total number of responses, large range of responses, perceived conflict of interest by respondents, overestimated service times, inaccurate survey vignettes, inappropriately high-value comparison code selections, and extremely long periods between initial and updated code valuations.

Further, CMS expresses concerns about the inability of the system to account for efficiencies gained over time in work RVUs and non-time-based services. The agency believes that non-time-based services such as procedures, radiology services and diagnostic tests, become more efficient as the professionals gain more experience, technology is improved, and other operational refinements are implemented. The efficiency adjustment is proposed to address these perceived efficiency gains that CMS feels have not been factored into code values. The efficiency adjustment would cumulatively

[1] 2023 HRS/EHRA/APHRS/LAHRS expert consensus statement on practical management of the remote device clinic https://www.heartrhythmjournal.com/article/S1547-5271(23)02011-8/fulltext

apply the MEI productivity adjustment from the last five years to the work RVU and intra-service time of all non-time-based codes with few exceptions. This would reduce work RVUs and intra-service times of affected codes by 2.5%. The proposal notes the intent to apply a similar productivity adjustment lookback every three years going forward in perpetuity.

The ACC has multiple concerns with this proposed efficiency adjustment and will outline them below.

Unsupported assumptions and flawed methodology

The agency critiques the RUC process for valuation of CPT codes for lacking empiric evidence of the validity of its recommendations. Yet, the proposal states that non-time-based codes invariably become more efficient over time due to increased experience, new technology and operational efficiencies with no empiric or any other form of evidence of such efficiencies. Even if the premise of gained efficiencies were accepted, there is still no apparent evidence that such efficiencies are gained uniformly across all services at the same rate over the same period of time. The proposal states, "we understand that accruing efficiencies does not apply equally to all services . . ." yet ignores this admission in the application of the adjustment.

It could be argued that CMS applies many policies in the aggregate rather than to specific services. In fact, this is how a productivity adjustment is applied to the inpatient and outpatient hospital payment systems. The productivity adjustment applied in those facility payment systems is a wide-ranging, aggregated estimate of presumed efficiency across the entire non-farm economy. Given other circumstances, this could be an acceptable argument to apply such a productivity adjustment to the physician fee schedule just as it is to the hospital payment systems. However, the hospital payment systems also receive annual inflation-based market basket increases. While there are likely certain hospital costs that increased more than the inflationary update and others that increased less, the system reflects a representation, in the aggregate, of increased costs due to inflationary factors and reduces it by an aggregated assumption of increased productivity. If the majority of the physician fee schedule is to receive this productivity adjustment, then there should also be a guaranteed, inflation-based adjustment to the conversion factor and the budget neutrality threshold. That would require a change in law. Until that happens, a proposal such as this should not advance.

Unsustainability of Routine Application of the Efficiency Adjustment

The productivity adjustment applied to hospital payments partially offsets the always-greater inflationary increase. In this setting, the adjustment only diminishes the inflationary growth of hospital reimbursements, it does not entirely negate them. Applying the efficiency adjustment reduction on a routine basis with no inflationary or other positive update will create unsustainable fiscal pressures and eventually deplete the work RVUs and times of affected services to near zero.

Destruction of Relativity

By reducing values/minutes of most but not all services, this proposal will create distortions in the fee schedule and diminish the ability of services to be compared against one another in a relative value system. Each service is meant to be valued relative to the rest of the fee schedule. Making an efficiency adjustment in this manner will compress work RVUs over time. A service valued at 1.00 work RVU will become 0.975 while one valued at 10.00 will become 9.75 RVUs. The service that was previously 9.00 RVUs higher is now 8.76 RVUs higher under this proposal. The 1.00 service has the same percentage reduction but has fallen 0.025 RVUs while the 10.00 service is 0.25 RVUs less. As these adjustments continue, the difference between these—and all—services will continue to shrink and it will become impossible to make comparisons between services, especially to services that are exempt from the efficiency adjustment.

Exemption of E/M Services

The exception of time-based services from the efficiency adjustment proposal is logical in that a code that requires 20 minutes can only be billed if that minimum time threshold is crossed. If the service becomes more efficient and the threshold is not crossed, one may not bill that service. E/M services may be billed by time *or* by medical decision making. Most E/M services are selected based on medical decision making. No discussion of that duality is offered in the proposed rule. Insofar as E/M visits could be expected to become more efficient when medical decision making advances with the use of technology like EHRs, care algorithms, or point-of-care clinical decision support, and other factors, it could be more accurate to also apply any efficiency adjustment to E/M services.

Applying the Efficiency Adjustment to Services Initially Valued or Revalued During the 5 Year Look Back

CMS proposes to apply the efficiency adjustment to codes that have been reviewed within the 5-year look back period, including codes proposed for revaluation this year. The given rationale is that "many of the challenges discussed previously in this section, namely reliance on survey data, still apply." While the proposal makes note of a multitude of concerns with the RUC valuation process, the main reason given for applying this efficiency adjustment is the process not accounting for changes in time and effort as efficiency is gained through experience. The main evidence for this supposed lack of accounting for efficiency gained through experience is the significant amount of time between valuations of services.

The RUC has a process by which codes are reviewed via the Relativity Assessment Workgroup (RAW) which brings many procedures up for review for potential revaluation. Services are also routinely revalued when new procedures are added to their family of codes. The agency notes in the proposed rule that even when codes are reviewed, the RVUs only go down 39% of the time. The latest report of the RAW, dated May 2025, notes that 38% of potentially misvalued codes are decreased. However, the report also notes that 19% of these codes are deleted. Therefore, 57% of codes reviewed are either decreased or deleted entirely.

The premise that adjustment is necessary to account for gained efficiencies that are not captured due to the length of time between revaluations should logically not be applied to codes that were revalued during the look back period as they were assessed during that time and updated with new times and values. The majority of the time, these reviewed codes are either deleted or decreased in work RVUs. To look at the codes in question is a study in why adjustments to code values should be done case by case considering each service's specific circumstances. The cardiology codes revalued during this look-back period have had a wide range of outcomes. Some services, such as complex PCI procedures, saw RVUs increase, with good reason. Certain services have evolved to be performed through new access points that were found to provide better outcomes for patients and reduce complications but in some cases requiring significantly longer time. Other services have seen their RVUs reduced by more than 10 times the proposed efficiency adjustment percentage. Notably, certain cardiac ablation procedures and left atrial appendage closure had work RVUs reduced by more than 26% through the revaluation process during the proposed five-year look back.

The rationale for applying the adjustment to codes revalued during the look-back period steers away from the initial justification for the adjustment, that being the time gap in valuation which fails to account for gained efficiency. Instead, this application of the adjustment is rationalized by referring to all the points CMS had laid out challenging the reliability of the survey data upon which value recommendations are based. CMS is stating that the underlying survey data on which all procedures in the PFS are based are so flawed that they cannot be trusted to update values over the look-back period. This is, in some cases, perplexing as the RUC established review process has led to certain codes (such as cardiac ablations) being reduced by 1000% of the aggregated efficiency adjustment upon re-survey and re-valuation. (A more than 25% revaluation reduction vs. 2.5% efficiency adjustment)

The ACC appreciates CMS's concerns about the accuracy of the fee schedule and desire to see updates made that reflect evolutions in care. Innovations can and should be made, but this proposal will not actually further accuracy. With engagement from across the medical field, such efforts could be fruitful in the future. **The ACC does not believe CMS should apply this efficiency adjustment in the sweeping manner proposed. The College believes that if such an adjustment is implemented, it should be paired with an inflation-based update. If such an update is not within the current statutory authority of the agency, then this efficiency adjustment should not be implemented until such authority is granted or an inflation-based update is implemented legislatively. If the efficiency adjustment is finalized, it should not be applied to any codes which had been initially valued or re-valued during the five-year look back period.**

<u>Updates to Practice Expense (PE) Methodology – Site of Service Payment Differential</u>

While CMS does not propose to incorporate the PPI and CPI survey data into PFS rate-setting for CY 2026, a significant and disruptive refinement to the PE methodology is proposed instead.

The rule summarizes that many services have a site of service payment differential between the facility and non-facility settings under the PFS. In the facility setting the payment rate includes

physician work RVUs and the indirect practice expense allocated based on the physician work RVU. While direct costs in the facility setting are paid through other payment systems, indirect costs allocated to services furnished in the facility setting are meant to reflect the typical costs associated with practice expenses in that setting of care. When the PFS was established, the methodology for allocating indirect PE was based in part on an assumption that the physician maintained an office-based practice even when also practicing in a facility setting.

CMS notes that physician practice arrangements have shifted significantly to hospital employment or integration during the intervening years, spurring concerns that allocation of the same amount of indirect PE based on work RVUs in both settings may overstate the indirect costs incurred by facility-based physicians if it is now less likely they would maintain an office-based practice separate from the facility practice. As such, CMS proposes to reduce the portion of the facility PE RVUs allocated based on work RVUs for services valued in the facility setting under the PFS to half the amount allocated to non-facility PE RVUs beginning in CY 2026. Additional information is also sought regarding the types and scale of indirect costs that are attributable to physicians who practice in part or exclusively in a facility setting, and whether reducing the portion of the facility PE RVUs allocated based on work RVUs to half the amount allocated to non-facility PE RVUs is an appropriate reduction or some other percentage should be considered in future years.

This policy change would have a dramatic impact, with total PFS payment in the facility setting decreasing by 7 percent, while non-facility-based payments would increase by 4 percent. **The ACC urges CMS not to finalize this proposal as this proposal does not accurately reflect resource costs incurred by practices in the facility setting and creates dramatic, unsustainable impacts to many individual physicians and other health care professionals.** Instead of making a large and arbitrary change that appears significantly informed by MedPAC simulations and modeling, CMS should obtain reliable data that firmly demonstrates whether any overstatement of indirect costs is actually occurring and find accurate and precise mechanisms to adjust payment accordingly. Applying the PPIS data or working with AMA and medical societies to address CMS's concerns through additional discussion, analysis, and/or data collection are the best mechanisms to so improve payment accuracy.

<u>Misunderstanding of Physician Practice Arrangements</u>

The ACC believes the proposed site of service payment differential policy represents a fundamental misunderstanding of the way physician practices—including those employed or highly integrated into hospitals—are organized.

First, most physicians are not direct employees of hospitals. Even at large academic institutions, physician groups are separate entities. They may be partially or wholly "owned" by a hospital, but the practice is a separate organization from the hospital. The practice has its own tax identification number and organizational structure within the hospital.

Second, even in practices that are partially or wholly owned by a hospital, the physician practice indirect PE exists discretely from the hospital. Every service line in a practice must cover all the

expenses that constitute its indirect PE overhead. Specific expenses are attributed to a practice/service line for rent or building depreciation costs. Administrative staff support the physicians in scheduling patients for procedures and office visits using software and computers. Billing staff code and submit claims. Building personnel maintain the physical environment. Utility costs for internet, telephone, water and electricity are incurred.

Third, hospitals are highly effective at identifying which costs belong to physician practices that must be covered by the revenue they generate. Those costs do not overlap with the hospitals' indirect costs. (In a hypothetical where those costs and payments did overlap, it would be just as valid to reduce payment to hospitals for this redundancy as it would be to reduce physician payment. Perhaps such a reduction could be evenly divided, if it could actually be quantified.)

Arbitrary Selection of 50% Reduction in Formula

It is unclear what data or evidence informed the decision to propose reducing by 50% the indirect PE RVUs allocated based on physician work RVUs. No study or report ACC could identify suggests that specific reduction to services valued in the facility setting is accurate. CMS has noted in the past several rulemaking cycles that the RAND Corporation is evaluating ways to analyze and develop alternative methods for measuring PE to inform updates to payment under the PFS. This change could stem from that work, but it is not stated. Instead, the reduction of this component of the fee schedule by 50% appears arbitrary. Until more information and transparency is shared for consideration by the public to allow meaningful analysis and understanding of the proposed methodology revision, CMS should not finalize this change.

Blunt Reduction Rather Than Accurate Revisions

In the same way that the 50% reduction in this portion of the PE formula appears arbitrary and not seemingly informed by specific data, the change is a blunt shift that does not make the fee schedule more accurate. In a hypothetical scenario where some services are indeed more likely to lack the full complement of historical indirect PE—which the ACC thinks is unlikely given the above observation about practice arrangements—the proposed site of service payment differential policy does nothing to apply revisions accurately to services. It assumes every single service valued in the facility behaves identically. It is more likely that variability would exist for services provided in different regions/states, or by different specialties, or for certain diseases. This variability could be particularly notable in rural and underserved areas. A 50% reduction would not be accurate for every service, and CMS should only make changes it knows are accurate.

Opaque Application of Policy

It is not clear from the text of the proposed rule or any of the associated addenda materials posted by CMS which exact codes are affected by the policy. The text says, "for each service valued in the facility setting under the PFS." However, nearly every service is valued in the facility setting under the PFS. It would assist stakeholders if CMS posted a separate addendum for this proposal—or future, similar policies—that displays exactly which services are impacted. Most useful would be if

that transparency was accompanied with analysis that showed how a particular adjustment was identified.

Unintended Consequences

It is not explained in the proposed rule whether CMS views the change in physician practice ownership arrangements that underpin this proposal to be positive or negative for patient care or the health care system. The ACC cautions that a methodology change that—by our estimate—generally lowers the total RVUs for affected services by about 10% will almost certainly have secondary impacts. Affected physicians who provide complex hospital-based services are unlikely to simply accept such a cut and go about normal patient care. Some will retire. Some will look to gain efficiencies through consolidation and new ownership arrangements. Some will be more inclined to seek or accept private equity stakes. As the cardiology specialty saw a dramatic evolution in practice ownership and integration after the 2008 PPIS implementation, the ACC urges CMS to reconsider whether these and other unknown results are acceptable outcomes of the proposed site of service differential policy.

Summary

For all the reasons noted above, the ACC restates its opposition to the proposed site of service differential policy and urges CMS to not finalize this proposal. If such a redundancy can accurately be identified and reasonably addressed in future rulemaking, CMS should transparently show the data that inform those policy decisions so stakeholders like ACC can meaningfully engage with the process and improve the system. Further, as with other large-scale updates to the fee schedule such as implementation of updates from the PPIS in 2010, repricing of supplies and equipment in 2019, and increasing clinical staff rates in 2022, such a change should be phased in over several years to minimize disruption allow practices time to adapt.

Payment for Medicare Telehealth Services

Distant Site Billing Requirements

In both the 2024 and 2025 MPFS Final Rules CMS extended the expiration of a flexibility for telehealth practitioners to bill using their currently enrolled location instead of their home address when providing telehealth services from their home. We find no discussion of this issue in the 2026 MPFS proposed rule.

Maintaining the ability for practitioners providing telehealth services from their homes without re-enrolling in Medicare and disclosing publicly their home address is paramount. This is crucial for the safety and privacy of health professionals as there have been recent incidents of workplace violence in health care facilities where direct harm to nurses and other medical staff have occurred, as discussed in the 2025 MPFS Final Rule. In addition to safety and privacy concerns, should this flexibility expire a significant number of practitioners would need to update their billing address with their Medicare Administrative Contractor, creating an administrative burden which the

administration has noted on several occasions it seeks to reduce and/or avoid.

The ACC requests clarity on this issue in the 2026 Final Rule and strongly urges CMS to make permanent the ability for practitioners to provide telehealth services from their home and for these practitioners to use their currently enrolled address when billing for these services.

Direct Supervision via Use of Two-way Audio/Video Communications Technology

CMS proposes to make permanent the definition of direct supervision that allows "immediate availability" of the supervising practitioner using audio/video real-time communications technology (excluding audio-only), for all services under 410.26 except for services that have a global surgery indicator of 010 or 090.

The College has supported this flexibility since its inception at the beginning of the COVID-19 public health emergency and strongly supports finalization of this proposal to make the policy permanent.

Cardiac and Pulmonary Rehabilitation

The ACC has supported the provisional inclusion of cardiac and pulmonary rehabilitation services on the Medicare Telehealth Services List for the last few rule cycles and encouraged CMS to add the services permanently. **The College enthusiastically supports the proposed permanent inclusion of cardiac and pulmonary rehabilitation services on the Medicare Telehealth Services List.**

Telehealth Flexibilities Expiration

The ACC is greatly concerned with the coming expiration of telehealth flexibilities implemented during the COVID-19 PHE on September 30, 2025. Most notable among these are the originating site geographic flexibilities and coverage of audio-only services. While CMS updated regulations at §410.78(a)(3) to permanently change the regulatory definition of an interactive telecommunications system to include two-way, real time audio-only communication technology for any telehealth services furnished to beneficiaries in their homes if the distant site clinician is technically capable of using an interactive telecommunications system that includes, at a minimum, audio and video equipment permitting two-way real-time interactive communication between the patient and distant site clinician, but the patient is not capable of, or does not consent to, the use of video technology, that change is moot if patients lack the ability to receive telehealth services in their homes. These enhanced points of access, especially for patients in rural and under-served areas, are imperative to care. Many patients lack economic or geographic access to sufficient internet access to accommodate audio-visual communications or are unable to operate required technology to partake.

The ACC urges CMS to use any and all avenues under its authority to maintain these vital means of access—originating site geographic flexibilities and audio-only services—to care for Medicare beneficiaries.

Valuation of Specific Codes

Closure Left Atrial Appendage with Endocardial Implant (CPT code 33340)

The ACC believes that the RUC-recommended 10.25 work RVU, if adopted by CMS, will render this code misvalued as the April 2024 survey was flawed and should be repeated. This is not merely hindsight by the societies, as a letter was submitted to RUC chair Dr. Silva via RUC staff prior to the April 2024 RUC meeting expressing in detail the multitude of concerns the societies had with the survey before a valuation was arrived at by the RUC. (letter text included below).

In summary, the societies that participated in the survey of 33340 believed that the most viable comparator codes for the LAA closure procedure both for the reference services list (RSL) and as potential crosswalks were the percutaneous coronary intervention (PCI) codes and the lower extremity revascularization (LER) codes. Neither were available for either purpose as the PCI codes were being surveyed for the same meeting and the LER codes were on a RAW screen (for 6 years at that point) and under continuous review by the CPT Editorial Panel. As detailed in the letter, the societies are convinced that these restrictions led to a significant incongruity between the survey recommended RVUs and times as well as Key Reference Services that were not clinically similar to the 33340 procedure.

The letter further details an extensive list of potential crosswalks that were examined and reviewed by the societies, RUC staff and the pre-facilitation panel with reasons why each was not feasible. The full text of the letter is below:

"April 22, 2024

Ezequiel Silva III, MD
RUC Chair
330 N. Wabash Ave, Suite 39300
Chicago, IL 60611

Dear Dr. Silva:

At the request of the Relativity Assessment Workgroup (RAW) the American College of Cardiology (ACC), Heart Rhythm Society (HRS) and Society for Cardiovascular Angiography & Interventions (SCAI) surveyed CPT code 33340, *Percutaneous transcatheter closure of the left atrial appendage with endocardial implant, including fluoroscopy, transseptal puncture, catheter placement(s), left atrial angiography, left atrial appendage angiography, when performed, and radiological supervision and interpretation,* for this April 2024 RUC meeting. We had a substantial response rate of 247 complete survey responses. However, due to several factors which we will explain, this code has proven essentially impossible to value at this

meeting using standard RUC techniques.

There were several key issues in both creating the survey instrument and applying the survey data in a manner acceptable to both the societies and the RUC per established RUC standards and protocols.

Concerns with RSL and Results

First, in creating the reference service list (RSL) for this survey it appeared clear to our staff and advisors that two of the best groups of codes to be included on this RSL would be the percutaneous coronary intervention (PCI) codes and lower extremity revascularization (LER) codes. Unfortunately, the PCI codes are to be valued at this meeting as well so we could not include them in our RSL. We did include several of the LER codes and were told after submitting our materials and launching our survey that we should not have included these. The LER codes are and have been on a RAW screen since 2018. While they are not being surveyed for this meeting, RUC staff advised that we should remove them from our RSL. If we did not, and one of them was chosen we would have to account for this to the RUC at the April meeting. After review by our staff and advisors we did not change our RSL because to remove the LER codes would leave us with an RSL with far too few codes and far too large gaps in work RVU options. As it turned out, neither the first nor second key reference service (KRS) codes selected in the survey were LER codes.

The results of the survey yielded a 25th percentile work RVU of 16.00, intra-service time of 70 minutes, and a total time of 177 minutes. The current 33340 code has a work RVU of 14.00, intra-service time of 90 minutes, and total time of 183 minutes. The societies would not expect that the RUC would entertain a 14% increase in work RVU with a 23% decrease in intra-service time.

The concerns with the RSL limitations are highlighted by the survey first and second KRS choices. The first KRS is 93656, *Comprehensive electrophysiologic evaluation including transseptal catheterizations, insertion and repositioning of multiple electrode catheters with intracardiac catheter ablation of atrial fibrillation by pulmonary vein isolation, including intracardiac electrophysiologic 3-dimensional mapping, intracardiac echocardiography including imaging supervision and interpretation, induction or attempted induction of an arrhythmia including left or right atrial pacing/recording, right ventricular pacing/recording, and His bundle recording, when performed,* with a 17.00 work RVU, 180 minute intra-service time, and a 263 minute total time. The second KRS is 93581, *Percutaneous transcatheter closure of a congenital ventricular septal defect with implant*, with a 24.39 work RVU, 180-minute intra-service time, and 270-minute total time. Neither of these values and times appear to be useful as crosswalks or in valuing the 33340 code at this time.

Crosswalks and RUC Staff Assistance

The societies found a dearth of viable crosswalks to a code of this time and value within the 000 global period. Outreach was made to RUC staff to seek guidance and consider any alternatives. We found only two acceptable crosswalks and were advised by RUC staff that neither should be used. Our first suggestion was 92941, *Percutaneous transluminal revascularization of acute total/subtotal occlusion during acute myocardial infarction, coronary artery or coronary artery bypass graft, any combination of intracoronary*

stent, atherectomy and angioplasty, including aspiration thrombectomy when performed, single vessel, with a 12.31 work RVU, 70 minutes intra-service time, and 139-minute total time. RUC staff flagged that this code has been surveyed for re-valuation at this RUC meeting and crosswalk ought not be made to a code valued at the same meeting in another tab. The second suggested code was 93582, *Percutaneous transcatheter closure of patent ductus arteriosus*, with a 12.31 work RVU, 60-minute intra-service time, and 146-minute total time. This code is labeled as "do not use to validate for physician work." After providing this feedback, RUC staff offered to assist in identifying potential crosswalks for 33340. Below is a list of codes RUC staff provided. We show the codes, times, work RVU and reason we felt the crosswalk would not be found viable by the societies or the RUC.

CPT Code	Procedure	Intra-Time	Total Time	wRVU	Issue
33340 (current)	Left atrial appendage occlusion	90	183	14.00	Current values
33340 (survey)	Left atrial appendage occlusion	70	165	16.00 (survey 25th)	Survey results
33741	Atrial septostomy	55	150	14.00	X-walk would maintain code value despite notable drop in IST. Code value was crosswalk from 33340.
33900	Pulmonary artery revasc by stent, native connections	90	206	11.03	IST much greater than survey time
33902	Pulmonary artery revasc by stent, abnormal connections	90	209	14.00	IST much greater than survey time
37225	LER, femoral, popliteal artery(s) with atherectomy	118	186	11.75	IST much greater than survey time, Code on RAW screen
37229	LER, tibial, peroneal artery, with atherectomy	120	188	13.80	IST much greater than survey time, Code on RAW screen
37230	LER, tibial, peroneal artery, with transluminal stent	120	188	13.55	IST much greater than survey time, Code on RAW screen
37243	Vascular embolization or occlusion; organ tumor infarct	120	196	11.74	IST much greater than survey time
37244	Vascular embolization or occlusion, hemorrhage	90	166	13.75	IST much greater than survey time
49594	Repair of anterior abdominal hernia, strangulated	120	225	13.46	IST and Total time much greater than survey time
49595	Repair of anterior abdominal hernia, >10cm, reducible	120	230	13.94	IST and Total time much greater than survey time

49615	Repair of anterior abdominal hernia, 3-10cm, reducible	100	190	11.46	IST much greater than survey time
49621	Repair of parastomal hernia, reducible	120	220	13.70	IST and Total time much greater than survey time
61640	Balloon dilatation of intracranial vasospasm, initial	90	233	13.75	IST and Total time much greater than survey time, also includes a post-op visit
92924	PCI atherectomy	84	143	11.74	Code being reviewed at this RUC meeting
92933	PCI atherectomy w/stent	87	146	12.29	Code being reviewed at this RUC meeting
92941	PCI acute myocardial infarction (AMI)	70	139	12.31	Code being reviewed at this RUC meeting
92943	PCI Chronic Total Occlusion	92	151	12.31	Code being reviewed at this RUC meeting
93582	Patent Ductus Arteriosus closure	60	146	12.31	Code labeled as "Do Not Use to Validate Physician Work"
93583	Septal Reduction therapy	90	178	13.75	IST much greater than survey time
93620	Comprehensive EP eval w/Arrhythmia Induction	120	230	11.32	IST much greater than survey time

After an exhaustive search by staff and advisors we found no other crosswalks of the 000 global period that we believe both the societies and the RUC would find reasonable.

Pre-Facilitation Outcome

The pre-facilitation panel was also not able to identify any reasonable crosswalks within the 000 global period. The few that were offered had wRVUs that represented a greater proportional reduction from the current 33340 wRVU than the reduction in intra-service time and are hence unacceptable to the societies.

The societies suggested tabling this tab and delaying re-survey of the 33340 code until the PCI and LER codes are valued and finalized by CMS so they could be used in the survey RSL and as potential crosswalks. It was stated that there is no precedent for this length of delay. However, the PCI and LER codes themselves are examples of such delayed valuations. These were delayed for CPT revisions but, the societies strongly believe delay for the purpose of having appropriate codes available for proper survey construction and valuation is as worthy a cause. Further, the 33340 code being valued is not a newly created code nor was it revised at CPT prior to this valuation attempt. Therefore, there is not an inherent need for a new value to be established for the proper functioning of the Physician Fee Schedule at this time.

Once it seemed apparent at pre-facilitation that an acceptable direct crosswalk to a 000 global code was unlikely to be found, the idea of cross-walking to codes of other global periods was suggested. The societies are skeptical of this solution for several reasons. First, this approach defies RUC convention against using codes with different global period for valuation and would require a reverse-building block methodology which is also against RUC convention. Second, in the interest of exhausting all avenues in addressing this quite confounding code, the societies had searched for crosswalks of other global periods and found that after removal of RVUs associated with the global period visits there are not acceptable crosswalks here either. The societies firmly believe that to force a valuation through such unorthodox means would be a greater and more detrimental deviation from RUC process than the delay we seek. Finally, it is uncertain CMS would apply either of those valuations and it would be preferable to derive a value from a future survey.

Conclusion

The societies strongly believe that for the survey and valuation of the 33340 code to be valid, the PCI and LER codes must be available both as part of the RSL and as possible crosswalk options. Both code sets should be re-valued within the current cycle to have RUC recommendations offered, CMS final values established in the 2026 Medicare Physician Fee Schedule rule, and be active with updated values on January 1, 2026. As such, the societies request that the 33340 code be re-surveyed for the April 2026 RUC meeting when these integral code families will be available for use in said survey. Thank you for your consideration in this matter.

Sincerely,

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ACC RUC Advisor

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SCAI RUC Advisor

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HRS RUC Advisor"

The circumstances of the April 2024 survey of 33340 created unreasonable restrictions to the process of building a RUC survey instrument, leaving the tool invalid for its purpose of establishing an appropriate updated value for this code.

The ACC vehemently disagrees with the proposed work RVU of 10.25 for CPT code 33340. The College strongly urges CMS to maintain the code at its current work RVU and procedural times and for the code to be resurveyed at the January 2026 RUC meeting using the updated and finalized values for the PCI and LER codes sets as reference service codes and potential crosswalks to create a valid survey instrument and fair and accurate updated valuation of this service.

Lower Extremity Revascularization (CPT codes 37XX1-37X46)

The ACC appreciates and supports the CMS proposal to accept the RUC recommended work RVUs for all 46 new lower extremity revascularization (LER) codes.

CMS proposes accepting RUC-recommended direct practice expense inputs with two notable exceptions. CMS recommends reducing the number of drug coated balloons (SD382) for codes 37X10-37X13 and 37X18-37X21 from two to one as well as the number of drug eluting stents (SD379) for codes 37X33-37X34 and 37X41-37X42 from two to one. The agency points to perceived discrepancies and inconsistencies of required resources among services within this large new family of LER codes.

In both cases, the differences in recommended direct PE are not discrepancies or inconsistencies but rather appropriate courses of treatment for the typical scenario for each of these codes. The specific details of the clinical differences of the codes requiring differing supplies and equipment are delineated in the practice expense Summary of Recommendation forms and reiterated in commentary by the Society for Vascular Surgeons and the American Medical Association.

The ACC urges CMS to implement the RUC-recommended direct practice expense inputs for all 46 new LER CPT codes.

The LER code set includes a large number of high-cost supplies. CMS requests comments on whether they should create G-codes to describe the use of high-cost supplies. The agency also seeks comments on whether to use the Hospital Outpatient Prospective Payment System (OPPS) mean unit cost data (MUC) to establish prices for these services and their supplies.

For many years numerous medical societies, including the ACC, have encouraged CMS to create separately billable Healthcare Common Procedure Coding System (HCPCS) codes for high-cost disposable supplies priced over $500. **The ACC continues to encourage CMS to create codes for separate billing of high-cost disposable supplies with costs over $500.** A report is also pending from the AMA House of Delegates on this topic after continued attention has been focused on this topic in recent years.

Using OPPS cost data to price supplies in the MPFS may have merit and is worth investigating. However, we are concerned with exactly how direct parallels could be made from costs incorporated into various Ambulatory Payment Classifications (APCs) with and without complexity adjustment factors and differing status indicators to specific, complex services and supplies in the MFPS. **The College recommends that, should CMS aim to use OPPS cost data to price these services and supplies in the MPFS, it should provide a detailed and specific methodological proposal in future rulemaking to allow stakeholders to provide the necessary feedback to accurately establish reimbursement rates for these services.**

Baroreflex Activation Therapy (CPT codes 93XX4, 93XX5)

The College appreciates and supports CMS proposing the RUC recommended work RVU for code 93XX5. The College disagrees with the agency reduction of the RUC recommended work RVU for 93XX4 from the survey 25th percentile of 0.79 down to 0.65 which was derived from a crosswalk to the survey first key reference service, CPT code 93279. While the key reference code 93279 and 93XX4 have identical intra-service and total time, the survey indicated performers believe the new 93XX4 code is more intense and complex. Further, CMS argues in this proposed rule that most services become more efficient over time as providers become more familiar with the services as justification for the efficiency adjustment. It would stand to reason that, this being a newly created code, it would require more effort initially. If the efficiency adjustment is finalized and implemented, then the value would be decreased over time to account for expected efficiency gains and eventually bring the value in line with the current proposed crosswalk. If the efficiency adjustment is not finalized the code would still be reviewed in three years for validity as this code family was placed on the RAW new technology screen.

CMS proposes to change the clinical labor type from RN (L051A) to a blend of RN/LPN/MTA (L037D) which would lower the practice expense inputs. The agency points to the blended clinical staff type being utilized in both survey key reference codes of 93279 and 93281. We reviewed the procedure with providers who perform these services regularly and all were adamant that only an RN performs these clinical staff activities on patients undergoing these procedures. We suggest the same reasoning for this higher-level clinical staff input as the work RVU for 93XX4 – this new procedure on complex patients requires a higher level of intensity, effort, and skill at this time.

The ACC urges CMS to accept the RUC recommended work RVU of 0.79 for code 93XX4 and the clinical labor type of RN (L051A) for the practice expense of the 93XX4 and 93XX5 codes.

Coronary Atherosclerotic Plaque Assessment (CPT code 75XX6)

The College supports CMS proposal of the RUC recommended work RVU of 0.85 for code 75XX6.

For practice expense, CMS proposes a crosswalk code 77373 which it states closely approximates the OPPS assignment previously employed by Category III CPT code 0625T. The ACC agrees with the

CMS analysis that the practice expense portion of the service would not likely be adequately reflected under the current PE methodology, yet also finds this crosswalk solution to be problematic for its ad hoc approach and possible lack of stability if it is changed in future years. The $1,500 fee for the coronary plaque assessment Software Analysis is a cost paid by the practice for each patient who receives 75XX6. The software is not owned by the practice, essentially making it a high-cost supply. The ACC has previously recommended that CMS separately define and pay for high-cost disposable supplies and believes that approach would alleviate concerns about stability for this service, consistency across the fee schedule, and transparency as discrete items could be reviewed and updated on a regular basis. This would be similar to both Software as a Service commentary and other high-cost supplies discussed in the fee schedule.

Coronary Therapeutic Services and Procedures (CPT codes 92920-92943, 92973, 92X01-2, 93571-2)

The College appreciates and supports the CMS proposal to accept the RUC recommended work RVUs for all 12 codes including 92920, 92924, 92928, 92933, 92937, 92941, 92943, 92X01, 92X02, 92973, 93571, and 93572.

Remote Physiologic Monitoring (CPT codes 99453-4, 99457-8, 99091, 99473-4, 99XX4-5)

The ACC wishes to comment for the record that great efforts were made by all societies participating in the survey of the Remote Physiologic Monitoring codes to obtain an adequate survey sample. Over 14,000 surveys were sent and numerous follow-up reminder communications as well. The College also acknowledges that, despite these efforts, the survey response fell well short of the minimum required by RUC protocols. As such, the College agrees with the CMS proposal to maintain the current values of codes that were revised per this survey including 99091, and 99457; accept the RUC recommendations to maintain the current values for codes 99458 and 99474; and value 99XX5 on a proportional basis to code 99457.

The College does not object to the CMS proposal to apply Hospital Outpatient Prospective Payment System cost data to value CPT codes 99XX4 and 99454 given the challenges in obtaining substantial evidence of accurate costs by other means.

The ACC supports the proposed work RVUs for codes 99091, 99474, 99XX5, 99457, and 99458. The College also supports the proposed amendments to the PE inputs for 99XX4 and 99454.

Renaming Equipment Package

During review of inputs for remote physiologic monitoring by the RUC, it became clear that these services are increasingly diverse and the equipment package for physiologic monitoring is not generally used for heart failure patients. CMS proposes to make a change recommended by the RUC to change the name of EQ392 from "heart failure patient physiologic monitoring equipment package" to "patient physiologic monitoring equipment package." The ACC agrees with this shift toward a generic name and use and supports the proposal by CMS.

Evaluation and Management Visits Complexity Add-on (G2211)

In the 2024 Final Rule CMS implemented payment for complexity add-on code G2211 (*Visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious condition or a complex condition. (add-on code, list separately in addition to office/outpatient evaluation and management visit, new or established).* In our comment letter on the 2024 MPFS proposed rule, the ACC expressed concern that the estimated utilization of this add-on code of 38% of all reported E/Ms was extremely high and should be reduced significantly to not inappropriately reduce the Conversion Factor due to statutory budget neutrality requirements.

Analysis of the first 3 quarters of 2024 CMS claims data show that these concerns were well founded. Through the first three quarters of 2024 the G2211 code was billed on just 10.5% of E/M codes. The trend started below this level and increased each week for the first two quarters but did level off at approximately 13% for nearly the entire 3rd quarter. Extrapolating this trend out for the year demonstrates an approximately $1 billion dollar reduction to the MPFS due to the grossly overestimated utilization of G2211.

The ACC strongly urges CMS to correct the utilization estimate for G2211 based on actual claims data from 2024 by making a prospective budget neutrality adjustment to the 2026 CF in the MPFS 2026 Final Rule.

Payment for Software as a Service (SaaS)

CMS describes the advance and increasing use of SaaS algorithm-driven services that assist clinicians in making clinical assessments. Providers pay for SaaS on a per-use or subscription basis. This is in contrast to other software which has traditionally been purchased with hardware acquisitions or as add-ons to enhance features/services. New CPT codes have been developed for a variety of SaaS procedures. In some instances, the costs associated with the SaaS procedures exceed the costs of the underlying service that underpins the SaaS.

Citing the heterogenous, novel, and evolving nature of SaaS technologies, CMS states it is challenging to compare SaaS procedures to existing medical services for the purposes of rate-setting. Therefore, the Agency seeks public comment on several aspects of payment policy that would broadly apply to SaaS procedures. The ACC appreciates the Agency's efforts to devise a cogent strategy in this space and offers preliminary thoughts on the questions posed in the rule. However, more work and policy development are needed in this space, and the ACC looks forward to additional engagement on this topic.

What factors should CMS consider when paying for SaaS?

One factor CMS should consider is the direct and indirect costs incurred by a practice to utilize SaaS. This can include IT security infrastructure, IT professionals for linkage to software services,

workstation enhancements, etc. Some SaaS is provided on a per-click fee basis. Others may be offered as a subscription. Some SaaS capabilities are even built into purchased software. Mechanisms should be available to practices that allow those direct costs to be covered in whichever format the product is sold.

We cite the practice expense considerations first because our experience has been that SaaS fees are the main cost of these services.

Physician work is a second important factor that must be incorporated. The ever-present buzz that software and artificial intelligence (AI) are going to make medicine better and more efficient remains exciting and promising. For example, dictation and documentation assistants have already demonstrated utility, yet even these solutions require a meaningful degree of physician review and oversight to correct errors, ensure relevant information is included, and prevent inaccurate information from being inserted. In the cardiology space so far, most SaaS are additional calculations and services of existing imaging and diagnostic data. Generally, these services *add* to clinician work in pursuit of improved patient care, becoming a new report that must be interpreted and incorporated into care planning. This additional work must be recognized in some manner. That could be as a discrete service, a complicating element of an E/M, or some other approach. This trend also demonstrates an important point that ACC has made in other comments on AI in health care—clinicians and patients must retain decision making abilities when it comes to patient care. As AI capabilities continue to evolve, it is essential that policies reaffirm that clinicians and patients—not algorithms—remain at the center of care.

Finally, the robustness and relevance of SaaS is highly dependent on the input. For SaaS to be effective, it requires a strong underlying program with human experts and stringent quality control.

Given the limitations of the PE methodology to account for this kind of technology, what alternative pricing strategies should CMS use to accurately pay for SaaS and AI devices under the PFS? For example, should CMS continue its current practice, as referenced in section II.E.23. of this proposed rule, of crosswalking values from the OPPS established payment amounts for the technical components of services incorporating SaaS and AI? Or should we integrate OPPS geometric mean costs for these devices into our ratesetting methodology as we are proposing to do in this proposed rule for RPM and RTM services, or set payment rates relative to OPPS rates as we are proposing to do for radiation oncology services? See sections II.E.24. and 30. this proposed rule.

The ACC has grown increasingly concerned that the potential growth and cost of SaaS will rapidly increase and consume scarce health care resources. It remains uncertain what constitutes an appropriate mechanism to set pricing for these services. Is it the cost to research, develop, and implement a machine-learning algorithm amortized across some number of expected units of service to derive a return of some percentage on the required investment? If SaaS can avoid downstream costs, would the rate be the downstream costs saved? If so, how would downstream cost savings be assessed, as services are usually assessed by costs to deliver? Perhaps the price is simply whatever the market will bear?

In every instance to date with which ACC is familiar from member experience, it is unknown what determines the price a facility or practice is billed for an individual SaaS. Beyond the traditional components of supplies, equipment, and labor, the price of a unit of SaaS analysis appears to be a black box for which derivation of the invoiced price is unknown. The most common examples to date in cardiology SaaS are re-analysis of cardiac CT angiography studies, fractional flow reserve CT (FFRCT) and CT artificial intelligence coronary plaque assessment (AI-CPA)—which is addressed in this rule. The physician fee schedule technical component payment for the underlying CT study is currently $209 nationally. That is a service that includes clinical staff time, various supplies, and an expensive CT machine, software, and other equipment. The invoiced costs for the SaaS technical component of FFRCT and AI-CPA that provides new and enhanced information from those studies as a new service is roughly 5 to 7 times more expensive than the $209 PFS technical fee to obtain the data. In the same manner that technical fee costs must be itemized for services in the physician fee schedule, some new level of scrutiny seems to be necessary to better understand the price of SaaS items to ensure Medicare is getting value for beneficiaries.

Decisions will have to be made about whether the "costs" are represented by a subscription or per-click fee as opposed to inherent in purchased software or equipment. If a result obtained through SaaS can also be obtained through other manipulation of already-owned software tools, are the additional costs of that effort added to the traditional version of the service, or are they considered in the same pool as the SaaS? I.e., if CT software that accompanies a scanner has or develops the ability to do the same thing as SaaS that has obtained a dedicated billing code, does the software-based version qualify to bill the service even though the costs for that version are dramatically lower with the software functioning as a piece of equipment? Depending on the rate charged for SaaS, the inherent/derived versions may be much more affordable and there would be reasons and incentives to want to identify low-cost options.

The ACC views the use of OPPS payments for fee schedule ratesetting as a band aid to address niche problems or temporary knowledge gaps, not a durable solution. In general, OPPS payments would be expected to reflect the enhanced purchasing power of a hospital or health system, meaning there is a strong likelihood it would underpay for costs in the non-facility setting. It also masks the underlying problems with fee schedule payment for SaaS, which CMS must find a mechanism to address. In light of these considerations, the ACC recommends CMS consider isolating SaaS costs from the fee schedule in a manner similar to Part B drugs, with payment based on a different schedule, calculation, or prospective payment system.

How should CMS value the physician work associated with utilizing and interpreting the clinical outputs associated with SaaS and AI devices?

Physician work will vary depending on the exact type of service being performed,. In instances when SaaS utilizes existing data to generate outputs such as a new image, new data points, or new insights that a clinician analyzes and interprets to make care decisions, that work could be assessed similarly to traditional tests or imaging. In instances when SaaS uses large data sets to make care recommendations for patients, the physician work could be similar to E/M medical decision making. In either case, time, skill, risk, and psychological strain are all relevant factors to incorporate

into rate-setting. To date, this work has been significantly more than receiving an SaaS "score" in a report and then choosing one option over another based on a number; clinicians interpret data and reports to make diagnoses and care decisions. SaaS adds work for clinicians, creating additional information for consideration, rather than reducing work by simply telling clinicians what to do. While SaaS can identify efficiencies in straightforward cases, it does not replace human work. In more complex cases, experienced experts remain essential. Policies should recognize the balance and nuance in attributing effort and credit between expert human judgment and AI outputs.

The AMA has created the code classifications for various kinds of AI. They break AI into three categories: assistive, augmentative, and autonomous. More detail can be found at their website on the topic: https://www.ama-assn.org/practice-management/cpt/cpt-appendix-s-ai-taxonomy-medical-services-procedures.

How may CMS best evaluate the quality and efficacy of SaaS and AI technologies?

The CPT Editorial Panel process could generally be relied upon to describe effective services which are distinct from the underlying, base test or professional service fee or needing physician judgment and quality oversight for clinical adjudication. Part of the CPT application requires literature of a certain caliber that supports the efficacy of a service. Such parameters could be used by CMS. In instances where CPT is not utilized for some reason, it seems likely that stakeholders have every incentive to be in contact with CMS to identify appropriate solutions to recognize which analyses are effective. The ACC is concerned that many new SaaS technologies could quickly be seeking distinct coding options for services that fit the criteria to be a distinct service but may also have similarities to software that is purchased by an imaging lab or already included in equipment and subscriptions used to make similar assessments.

Ambulatory Specialty Model for Heart Failure

For over two decades, the ACC has been and remains committed to assisting our cardiovascular clinicians' transition to value-based cardiology care through creation of practice guidelines, appropriate use criteria, expert consensus statements and other recommendations. The College appreciates CMS and its Center for Medicare and Medicaid Innovation (CMMI) for their willingness to collaborate and respond to questions and feedback on prior quality and innovation models, including the Medicare Acute Care Episode Demonstration, Merit-based Incentive Payment System (MIPS), the original Bundled Payments for Care Improvement (BPCI), and BPCI-Advanced. Such engagements have provided improved alternative payment model experiences for our cardiovascular members.

Since establishing its first principles for pay-for-performance in the early 2000s, the College has prioritized ensuring that quality and value assessments are measured and rewarded at the practice level rather than the individual clinician. Over the years, the ACC, cardiology training programs, and medical practices have developed and cultivated the importance of team-based cardiology care. As a core tenet, each member (cardiologist, CV sub-specialist, advanced practice nurse, imaging

technician, pharmacist, and administrative staff as well as other medical specialties including primary care) serve vital roles to ensure the patient receives high quality cardiovascular care with access to necessary and timely medical attention, appropriate testing and medications. **Because of these important roles, we strongly encourage the assessment and evaluation of CV clinicians' performance occur at the level of a team/practice and not at the level of an individual clinician. Therefore, the College believes that the Ambulatory Specialty Model (ASM) as it is currently proposed to only include cardiologists as participants would create significant complexities for attribution, scoring, and comparison to other physicians.**

Additionally, it is vital for the model's participants to be incentivized, when appropriate, to follow well-established practice guidelines and recommendations including patients following guideline-directed medical therapy (GDMT), which will be discussed later in this comment letter. We are very concerned that the model, as currently proposed, has the potential to create adverse incentives to lower the cost of HF care in order to maximize scoring, and most significantly, would negatively affect patient care and outcomes. Furthermore, the ACC has significant reservations about the proposed model due to its inherent structure, which would result in nearly half of participating cardiologists receiving a negative payment adjustment if their performance scores fall below the median, regardless of any improvements in care quality or cost efficiency.

Considering the ongoing, productive collaboration between the College and CMMI, the following comments highlight areas of needed attention from clinical and practice perspectives with the overall aim to improve the current program.

Proposed Length of Model Test

CMS proposes that the ASM will run from January 1, 2027, through December 31, 2031, for the performance years, with corresponding payment years spanning January 1, 2029, through December 31, 2033. The College appreciates the five-year length of the model test, which allows for an adequate period for participation and data collection. It will be vital for CMS to provide timely and actionable data to all participants to allow adequate time for review, analysis and performance improvement throughout the course of the model.

Proposed Mandatory Participation

The College recognizes that CMMI's goal in proposing a mandatory program is to ensure broader participation and more consistent, applicable data than has been possible under voluntary models such as BPCI-Advanced or the MIPS Value Pathways (MVP). In those programs, participation was readily subjected to selection bias and limited sample size, as well as the option to withdraw before the end of the programs.

As seen in the QPP/MIPS, solo and small practices with limited resources and infrastructure may be disadvantaged in a five-year model, leading to lower participation and engagement. If mandatory participation is finalized, the College strongly urges CMMI to proactively reach out to those potentially disadvantaged participants who may face greater scoring penalties.

Proposed Participants/Heart Failure Cohort

Specialty Type Identification

We are concerned that CMS's proposed methodology for identifying ASM participants, particularly for the heart failure (HF) cohort, overly narrows eligibility by focusing on "cardiology" while excluding relevant cardiology subspecialists who provide essential components of HF care. This limited focus risks undermining the clinical validity and fairness of performance comparisons under the ASM model. Heart failure care is largely multidisciplinary and cannot reasonably be attributed to a single clinician.

As currently proposed, CMS would determine clinician specialty based on the plurality of Medicare Part B claims, which may inadvertently exclude certain subspecialists who play a key role in HF care, such as advanced HF/transplant cardiologists (Medicare Specialty Code C7) or those with dual specialties. For example, a clinician with a mix of general cardiology and HF claims could be misclassified if the largest share is only slightly higher for a general specialty code. Moreover, excluding subspecialists from ASM participation would not reflect the real-world team-based care models used in HF management. Initial diagnosis may occur in primary care, during a hospitalization, or with non-invasive cardiologists; but confirmation and subtyping typically require cardiology input. Advanced practice nurses may also be involved early in the care of the patient.

Heart failure diagnosis and management can include B-type natriuretic peptide (BNP) testing, echocardiography, risk assessment, medication titration, and comorbidity management. These occur across multiple clinicians and settings, with varying workflows depending on local resources. For example, primary care providers (PCPs) generally manage comorbid conditions, cardiologists adjust HF medications and monitor therapy, nurses and advanced practice providers staff the heart failure clinics and education programs, and subspecialists such as electrophysiologists, interventional cardiologists, nephrologists, and endocrinologists contribute based on patient complexity. If attribution is based narrowly on primary diagnosis codes or the first clinician encounter, it risks artificially reducing measured HF incidence and misclassifying which clinician is responsible for outcomes. This reality results in a "messy middle" of shared responsibility with a team-based approach, where multiple providers contribute to diagnosis, stabilization, and longitudinal management. Accountability for costs is similarly distributed across team members, including imaging, procedures, hospitalizations, medications, and post-acute care.

Based on our experience with the CMS Quality and Resource Use Reports (QRUR), we found that many physicians are not classified correctly with their most recent specialty classification. Often, physicians keep their initial specialty designation (general cardiology) when starting at a new practice and often do not update it when their daily clinical practice evolves into a cardiology subspecialty classification of interventional cardiology, electrophysiology, advanced heart failure and transplant. The College often sends members reminders to update their specialty types in PECOS for Medicare and other payers.

Therefore, we caution against limiting eligibility or performance assessment strictly by specialty code. Specialty codes based on plurality of claims can be misleading, especially for multi-specialty providers or those working across different locations. CMS should also clarify how clinicians who move TINs mid-year will be tracked and how credit (or penalties) will follow them. To more accurately identify the managing clinician, CMS could supplement the specialty code with additional information, such as HF diagnosis and E/M mix, patient relationship codes, registry/QCDR participation, and relevant board certification to identify the clinician managing the patient.

In addition, under the proposed ASM, an individual clinician who assigns billing rights to multiple TINs would be treated as separate participation entities and required to meet reporting requirements for each applicable NPI/TIN combination. The College believes that such a rule creates an unneeded and concerning level of complexity for clinicians and their practices. We strongly encourage CMMI to follow the MIPS structure which calculates the clinician's scoring for each TIN, then selects the higher score and omits the lower scores for assessment and comparison. If CMS finalizes NPI-level mandatory participation, selected participants should receive a preview period for attribution/comparator assignment, a formal reconsideration mechanism to correct specialty designation and episode attribution, the ability to exclude non-managing episodes, and protection from penalties during the appeals period. **Ultimately, the ACC strongly recommends CMS assess participants at the practice or TIN level which would support the current standard of practice.**

Episode Based Cost Measure (EBCM) Volume Threshold

To promote consistency between MIPS/MVPs and the ASM, the College supports CMS's use of the HF EBCM to determine ASM participation eligibility. Building on the attribution considerations, the proposed 20-episode volume threshold may also raise challenges. While 20 episodes may be a reasonable starting point, it may not adequately reflect the variability in cardiologists' practice patterns across rural, urban, or hospital-based settings. Subspecialists who manage HF patients episodically or as part of a team may fall below this threshold, despite delivering meaningful care.

Several physician members of the ACC participated in the HF cost measure field testing process through CMS' consultant, Acumen. Based on the current cost measure's attribution methodology, the data showed that cardiology was attributed to just over 51% of HF cases. Other specialties such as internal medicine, interventional cardiology, family practice, nurse practitioner, and cardiac electrophysiology accounted for approximately 48%.

Considering the field-testing attribution results and the ASM as proposed, only half of the HF patient population would be attributed to a cardiology specialist with the other half being allotted to a cardiologist who may not be actively managing a patient's specific longitudinal HF care. The College is greatly concerned that this attribution process will greatly impact long standing patient and physician relationships as well as clinician to clinician collaboration. A more accurate approach would be to attribute the patients at the TIN level rather than the individual physician level to recognize the shared accountability across the multidisciplinary team and the system of care for the management of patients with HF.

Selection Methodology

In a recent analysis published in the *Journal of the American College of Cardiology*, it was found that nearly half of U.S. counties do not have a practicing cardiologist.[2] Additionally, 86.2% of rural counties had no cardiologists, and the average round-trip distance to the nearest cardiologist was 16.3 miles vs 87.1 miles in counties with and without cardiologists, respectively. CMS has also asserted that more than one-third of the CBSAs (359 out of 959) would be excluded completely from selection, because there were no clinicians in those areas who had the minimum number of episodes in the year 2024 analysis.

The lack of practicing cardiologists is apparent to some communities of Medicare beneficiaries, especially rural areas. The round-trip distance to a cardiologist as well as the location of the patients' medical services can be considerable factors for participating in the ASM. For an attributed patient with HF, there is a strong presumption that longer distances indicate the patient is less likely to receive most of their medical care near the attributed cardiologist, especially with urgent visits and hospital admissions.

Given these concerns and the current attribution method in the HF EBCM, the College urges CMS to reconsider how geographic areas are assigned to clinicians. Attribution should reflect the physician delivering the dominant portion of a patient's HF care, rather than defaulting to the only cardiologist involved in the care arrangement. We are very concerned about scenarios where the ASM participating cardiologist meets the required number of services to satisfy the EBCM attribution standard, yet the patient lives more than 50 miles away and receives most care from a local primary care physician and hospital. The distant cardiologist should not be attributed to that patient.

Lastly, the current ASM proposal introduces a very complex and potentially burdensome attribution method for a cardiologist participant. The participant and their practice will need to determine the patient's insurance status for traditional Medicare and the number of claims filed per 180 days as well as the number of prescriptions written for the patient. Finally, if the patient receives most of their HF services within the geographically selected area, the ACC requests that this process be made easier to track and identify the ASM areas as well as the attributed patients. We also ask that CMS study the applicability and utilization of patient relationship codes, which are coded by a clinician to indicate their level of involvement with the patient's care to factor into patient attribution.

Proposed ASM Performance Assessment Approach, Data Submission Requirements, and ASM Performance Category Requirements and Scoring

[2] Kim JH, Cisneros T, Nguyen A, van Meijgaard J, Warraich HJ. Geographic Disparities in Access to Cardiologists in the United States. *J Am Coll Cardiol.* 2024;84(3):315-316. doi:10.1016/j.jacc.2024.04.054

ASM Performance Categories

We appreciate CMS's effort to align the ASM scoring framework with existing MIPS structures, as well as the overall goal to improving value. However, shifting individual clinicians into a model where 100% of scoring rests on Quality and Cost for a small heart-failure cohort is a sharp departure from prior MIPS and MVP experience. In the recent 2023PY QPP Experience Report, data shows that cardiologists have been slow to adopt and submit the Advancing Care for Heart Disease MVP: 731 registered, yet only 38 cardiovascular clinicians received a final score in the 2023 performance year. Launching a mandatory, two-sided risk model that relies heavily on similar measurement and attribution mechanics raises concerns. While this MVP provides an important foundation, current participation trends highlight a need to optimize and provide further education on the MVP and this ASM to better support cardiologists in transitioning to value-based care.

Data Submission Requirements

We are concerned that requiring data submission strictly at the TIN/NPI level, rather than allowing group, subgroup or registry-level aggregation, may underrepresent the team-based, multispecialty nature of cardiovascular care. Cardiologists often participate in shared care models where improvement activities or interoperability efforts are implemented at the practice or health system level. CMS should consider allowing reporting at the TIN level for certain performance categories to better reflect the collaborative nature of specialty care delivery.

Proposed Quality ASM Performance Category

Quality Measures

The ACC supports the inclusion of condition-specific, clinically relevant quality measures in the ASM HF cohort, particularly CMS's effort to align the model with contemporary HF care. The proposed set covers several essential measures, such as evidence-based medications, blood pressure (BP) control, and functional status. That said, a few updates would make the set more guideline-concordant and fair in a two-sided risk model without adding burden.

The measure set would benefit from the inclusion of newer therapies such as statins and SGLT2 inhibitors in order to align with current therapy, as well as updates to topped-out measures. We refer the agency to the *2020 ACC/AHA Clinical Performance and Quality Measures for Adults With Heart Failure* for guidance on current pharmacological treatment as well as quality and performance metrics for HF, as these are reliable, valid, and are based on evidence-based guidelines. If feasible, a single GDMT composite would keep burden low, but consideration should be given to exceptions to meeting individual components of such a measure.

We recommend CMS allow scoring flexibility to avoid penalizing clinicians for isolated gaps in care delivery. Mandating that clinicians report on all five measures in the ASM HF set raises concerns about feasibility and data completeness. Not every measure applies to every patient, and missing data, exclusion bias, and reporting burden could distort performance results. For example,

cardiologists often care for hospitalized CHF patients that do not fit neatly into groups where GDMT has been studied. One of these groups is post-CABG patients who may not tolerate certain GDMT drugs. This may inappropriately skew the GDMT compliance of cardiologists because post-CABG patients should not be given every type of medication in the GDMT arsenal. This nuance may vary widely from cardiologist to cardiologist

A more practical approach would be to allow the physician to select between 3-5 measures relevant to their patients. We also urge CMS to ensure alignment between quality and cost scoring to avoid duplicative accountability under the HF EBCM. It should be noted that the proposed quality measures account for patients younger than 65, while the cost measure is for those above that threshold.

CMS should also clarify whether the proposed medication-based measures would apply to all HF patients under a clinician's care, or only to those attributed to the clinician under the ASM. Applying these measures broadly across all HF patients could significantly increase reporting burden and create misalignment with the attributed cost population, while limiting them to the attributed cohort may raise issues of sample size and representativeness. Clear guidance is essential to ensure consistent application and fair assessment. Similarly, the College strongly encourages broad flexibility or an established glide path for ASM participants on collecting, validating, and submitting their quality measurement data. According to the 2023PY QPP Experience Report, MIPS quality measures #5 and #8 were reported by participants only 1,197 and 1,008 times, respectively, with comparable results in previous performance years. Such low reporting volumes and limited engagement raise concerns about data accuracy and the reliability of these measures.

Finally, there will likely be a need for active support from ASM participants' practices, health systems, and EMR vendors to accurately collect data for provider-reported measures. Given the previously noted low reporting rates, many MIPS participants place little emphasis on these measures. Contributing factors may include insufficient staff training, limitations in EMR infrastructure, and concerns about the reliability of reported results. Since ASM participants are required to report these measures starting in their first year, the College requests a reasonable transition period to support successful data submission.

The ACC offers the following comments on specific measures:

1. #492 – Risk-Standardized Acute Unplanned Cardiovascular Admissions (Claims-Based)
Attribution at the TIN/NPI level, particularly for specialists working in team-based settings, may misrepresent individual accountability for admissions that are influenced by broader social risk factors or primary care coordination. CMS should monitor for unintended disparities and ensure risk adjustment accounts for factors outside cardiologists' direct control. Additionally, CMS should clarify how #492 scoring will interact with COST_HF_1, to prevent overlapping penalties for the same utilization events across quality and cost domains.

2. #008 – Beta-Blocker Therapy for LVSD (Process)
This is a foundational GDMT measure that has strong evidence behind it. That said, beta-blocker use is widely adopted and nearing topped-out status in many reporting situations. CMS could consider transitioning this measure toward an outcomes-based construct (e.g., persistence, adherence, or optimization of dosing), particularly if it is to be retained across the duration of the model. In addition, this measures patients only with reduced ejection fraction.

3. #005 – ACEi/ARB/ARNI Therapy for LVSD (Process)
ARNIs have a demonstrated benefit in patients with HFrEF. However, similar to #008, CMS should explore ways to evolve the measure over time, particularly since it is topped-out. A composite adherence measure or PRO-linked construct may more effectively reflect the value of GDMT in practice, rather than relying on prescription documentation.

4. #236 – Controlling High Blood Pressure
While blood pressure management is important to HF control, #236 is also influenced by documentation workflow issues and patient noncompliance. We suggest updating it with risk stratification or digital quality components to address disparities and other challenges, and also consider accepting home/remote BP. Additionally, CMS should clarify whether a missed reading due to a single skipped visit or lack of patient engagement would disproportionately impact performance scores under ASM.

5. #377 – Functional Status Assessment for Heart Failure
Functional status is a key aspect of patient-centered care and an independent predictor of readmission and mortality. Scoring this measure in the ASM, however, risks penalizing clinicians for limitations in data capture rather than care quality. In the 2023PY, only a handful of CV clinicians (8 total) reported this measure, with an average score of three points (max 10). This indicates feasibility and benchmarking issues, not performance. CMS should phase this in as reporting-only, or possibly an improvement activity.

We recommend CMS prioritize development of a validated PRO-PM (e.g., based on the Kansas City Cardiomyopathy Questionnaire [KCCQ] or the Minnesota Living with Heart Failure Questionnaire [MLHFQ]) and pilot its use early in the ASM program. This would demonstrate a meaningful shift from documentation-based processes to measures of patient experience and lived health outcomes. However, it should be noted that the KCCQ and MLHFQ require purchasing licensing for their use in clinical settings. In addition, different data sources (EMR vs. registries) produce inconsistent outputs. Until these challenges are resolved, functional status assessment should be approached cautiously to avoid inequitable scoring.

Other Measures Under Consideration

We appreciate CMS's thoughtful consideration of additional measures for the ASM HF cohort. We recommend against including Patient Activation Measure (PAM #503) at this time due to concerns about burden, access, and questionable attribution. Similarly, while advance care planning is important, we agree that #047, Advanced Care Plan, is better suited for primary care settings and

not ideal for attribution to cardiologists. We support CMS's decision not to include the Multiple Chronic Conditions (MCC) admissions measure (#484), which is insufficiently targeted to HF care. Finally, CMS could include #243 (Cardiac Rehab Referral) as an optional or adjusted measure, given its strong clinical value and evidence base, provided CMS addresses access-related inequities. These inequities could be addressed by including numerator credit for things such as e-referral or documented patient choice/clinical contraindication, applying hardship exceptions for no available or distant programs, and stratifying results by geography or dual-eligibility. It could also be considered for Improvement Activity credit.

Data Completeness Requirement of 75 Percent

We support CMS's goal of ensuring that quality measure results are based on a representative sample of patients. **However, we recommend caution in implementing a strict 75% data completeness threshold without appropriate flexibilities for specialty clinicians.** In cardiology, clinicians often provide episodic, consultative, or co-managed care, particularly in hospital-based or multispecialty group settings. In these cases, full documentation of all required fields may not be consistently available to the cardiologist, despite high-quality care being delivered. We also stress that since this requires reporting from individual clinicians who may not be well-versed in reporting these specific measures, some flexibilities should be implemented, especially in the first year or two. A phase-in approach (e.g., 50% in PY1, 60-65% in PY2, etc.) will help keep the spirit of reporting while avoiding burden or inequity.

Denominator exceptions could be created (e.g., an "unknown/not available" data element) when information is not accessible to the cardiologist so that incomplete records are not considered "failures". To ensure fair and feasible participation, we urge CMS to maintain flexibility in reporting options for the ASM model. Clinicians should be allowed to report via registries or other validated mechanisms, not just through EHR-derived eCQMs, particularly while digital infrastructure continues to evolve. We also recommend CMS provide clear technical guidance, allow for a transition period, and consider hardship exemptions for clinicians facing issues with vendors or barriers with integration into workflows.

Scoring, Benchmarking

We appreciate CMS's attempt to align quality scoring with established methodologies from MIPS and MVPs, though some concerns are inherent with the methodologies proposed for the model. To begin, separate benchmarks by scoring types makes sense, though it may unintentionally penalize clinicians who adopt certain reporting pathways that perform differently due to measure specifications or data completeness. Given that the median performance of all participating physicians and the Part B payment amounts for each physician would not be known until after the performance year, this would be challenging for physicians to contemplate whether they will receive a penalty, bonus or no payment adjustment. We suggest that in the initial performance year, physicians in the ASM obtain scores similar to physicians in all Medicare pay for performance programs.

The proposed 20-participant threshold may still be insufficient to generate stable benchmarks for certain measures, so the College recommends safeguards or confidence intervals for measures that may demonstrate wide year-to-year swings. Clinicians will also need access to initial benchmark ranges early in the performance year to have a clear guide as to what would be considered meaningful improvement.

We understand CMS's hesitation to prematurely label measures as topped-out within the ASM due to the different reporting dynamics. However, for measures that are historically topped-out in MIPS, CMS should closely monitor whether similar patterns emerge and consider early mitigation strategies. These could include narrowing measure definitions, transitioning to outcome-focused specifications, or suppressing topped-out measures from final scoring to avoid clustering. We support CMS's proposal to remove measures from scoring if data are compromised by external errors (e.g., code omissions, EHR glitches, guideline changes). This policy will help maintain the accuracy and credibility of final performance scores. Even in a mandatory reporting environment, topped-out measures can reduce the meaningfulness of comparisons, especially when used for public reporting or financial adjustment.

Cost Measure

Because the HF EBCM was recently finalized for MIPS in 2024, we suggest closely monitoring measure performance and attribution accuracy before using it as a mandatory threshold for ASM participation. Using a newly implemented cost measure to trigger mandatory model inclusion raises concerns about unintended financial or participation consequences if the measure has not yet been fully validated in real-world practice.

Clinicians who manage medications, schedule follow-ups, or coordinate care might end up with higher total costs for a patient's care because those improvements can lead to more office and virtual visits, diagnostic tests, home health services, or technology for remote monitoring. These are often the interventions that prevent emergency department visits and hospitalization admissions but may increase costs in the short term.

The College is very concerned about the inclusion of Part D medications and potential unintended consequences related to them. For fee-for-service Medicare beneficiaries, access to prescription medications varies widely, with many patients relying on supplemental coverage such as Medicaid or employer-sponsored retiree drug plans or otherwise paying out of pocket. In some cases, the ordering physician may provide limited samples or assist the patient in applying for a pharmaceutical manufacturer's patient assistance program.

The College strongly supports GDMT for HFrEF patients as outlined in the *2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure*, which recommends these four drug classes: renin-angiotensin-aldosterone system (RAS) inhibitors or angiotensin receptor-neprilysin inhibitors (ARNI), beta-blockers (BBs), mineralocorticoid-receptor antagonists (MRAs), and sodium-glucose cotransporter-2 (SGLT2) inhibitors. The guideline mentions that these "four pillars"

of therapy work together to improve heart function, reduce hospitalizations, and decrease mortality by lowering the heart's workload and altering the progression of the disease.

Of the four drug classes, at least two can have significant patient costs and copays with and without prescription coverage, which can obstruct or halt the patient's ability to follow the recommended HF therapy. Furthermore, these variations in prescription coverage will cause fluctuations in the ASM HF costs of care. Those patients with adequate Part D coverage will count towards the patient's annual ASM HF spend, while those with third-party medication coverage or charity care will not be counted. This scenario may cause risk of penalty. There should be class-level adjustments or "carve outs" so that supporting GDMT does not worsen performance within the program. We recommend that CMS continue refining EBCM attribution, exclusions, and risk adjustment to ensure they reflect the nuances between cost and clinical appropriateness, especially in high-risk populations such as older adults with multiple comorbidities.

Additionally, the HF EBCM may not yet fully account for patient severity beyond HCC codes, such as frailty or social risk; region-specific care patterns (e.g., differences in access to post-acute care); and changes to outpatient care plans, which can increase costs but improve outcomes. We ask CMS to consider publishing more detail on how risk adjustment differs between MIPS/MVP and ASM versions of this measure, and whether additional refinements are being considered to avoid penalizing clinicians who take on more complex patients or improve care access.

Next, the College request clarification on how benchmarking will be applied when the same measure is used in different models but with distinct clinician populations. Specifically, the HF cost measure was originally developed across a broad base, including attribution to other clinicians. In measure testing, the top five attributed specialties (percent of all episodes) were: cardiology (54.1%), internal medicine (14.8%), interventional cardiology (7.9%), cardiac EP (7.9%), and family practice (5.7%). While cardiology carries the majority of attributed episodes, the distribution across a range of specialties demonstrates that this measure impacts a broad set of clinicians beyond the primary specialty. CMS could show how benchmarks shift to illustrate these differences.

Benchmarking that compares only cardiologists could make the rankings higher or lower than they should be, especially for individual clinicians, which could make scores less consistent and possibly misleading. We recommend CMS share these effects, particularly since the proposed methodology is designed with performance bands relative to median costs ± standard deviations. During measure testing, the measure did meet the "high" reliability threshold at the TIN level (0.71 at a 20-case threshold), reliability at the individual clinician (TIN-NPI) level was lower at 0.62. This falls below CMS' 0.7 "high" reliability threshold, indicating that a meaningful proportion of variation in scores at the individual level is attributable to statistical noise rather than true differences in performance. Using a measure with only moderate reliability for high-stakes individual scoring could lead to misleading conclusions and unintended consequences.

CMS should also consider that the cost measure includes patients with preserved ejection fraction and not reduced ejection fraction as referenced in the two medication quality measures. CMS should either stratify the costs results by EF phenotype or add HFpEF-appropriate quality measures. If

CMS intends to move forward, we strongly encourage development of a more granular, specialty-specific benchmarking approach that reflects clinical realities and avoids applying measures validated in one population to another with different practice patterns and patient profiles.

Proposed Improvement Activities

We understand CMS's aim to strengthen coordination between specialty and primary care and to ensure health-related social needs are addressed. These are the right priorities for patients with chronic cardiovascular disease. To be successful, however, the activities should align with how specialty teams work daily, minimize new documentation burden, and avoid holding specialists accountable for tasks that are more suitable for primary care. We offer the following comments on the two improvement activities:

Improvement Activity 1 (IA-1): Connecting to Primary Care and Ensuring Completion of Health-Related Social Needs Screening
Specialists can confirm the PCP on file, share a visit summary, and verify whether an annual HRSN screen exists, but should not be expected to conduct or manage HRSN screening in full. There should be clear exceptions, so specialists aren't penalized if a patient declines a PCP, lives in a PCP shortage area, or the PCP declines the screening. Also, a clinician should receive full credit via simple proof from the EHR/HIE plus a visit summary sent to the primary care physician within "X" number of days. This would avoid requiring the clinician to submit lengthy narratives. CMS could advise which HSRN screening tools are acceptable and provide the appropriate documentation so vendors can integrate these tools into a clinician's workflow.

Improvement Activity 2 (IA-2): Establishing Communication and Collaboration Expectations with Primary Care using Collaborative Care Arrangements
Many specialists share patients with dozens of PCP groups. CMS should allow one CCA at the TIN or health-system level to satisfy IA-2, rather than separate agreements with each PCP office. In addition, specialists should not be penalized for PCP action nor inaction. Credit should be applied only to what the specialist can control and not whether the PCP responds.

The College strongly encourages CMS and CMMI to develop improvement activities with real-time actionable data that permits the physician and their care team to review and provide real-time data to improve patient care and/or office protocols. Similar to BPCI-Advanced, MIPS, and MVPs, physician and patient attribution data from the ASM will not be available for review until two years after the performance year. Physicians caring for HF patients can be much more impactful and improve patient outcomes with current, actionable data. Typical data delays can be frustrating when seeing information from the past which could have improved a patient's care.

Promoting Interoperability

The College appreciates CMS following the well-established MIPS process for this performance category. As the model progresses over the performance years, we request a review of this category's usefulness for improving care for HF patients along with saving costs for the Medicare system.

Performance Category Weights and Scoring

Requirements to Receive a Final Score

Cost and Quality Weighting: We recognize CMS's goal of aligning incentives around cost containment and clinical outcomes through equal weighting of cost and quality categories (50% each). However, cardiologists may face challenges such as patient complexity, referral patterns, or post-acute care needs, especially given the nature of HF. Assigning 50% of the final score to cost is a significant departure from MIPS and MVP frameworks. This high-cost weighting may inadvertently penalize providers delivering guideline-directed, necessary care. In addition, the corresponding quality measures are highly limited in terms of contextualizing the costs. When cost measures dominate the final score without balancing outcome or appropriateness measures, the model risks promoting cost-cutting over clinical quality. The high-cost weight could disincentivize participation in managing complex patients. CMS could lower the cost weight to 30%, then raise it in increments over time. Also, since the IA and PI categories function solely as compliance checks, the potential for large negative adjustments could undermine otherwise strong performers in the cost and quality categories. Some clinicians, for example, may face structural or operational barriers to meeting IA or PI requirements in full.

Lack of Reweighting: The proposal to avoid reweighting and instead issue neutral payment adjustments when scores cannot be generated (due to case minimums or data availability) may reduce administrative complexity but limits flexibility. In cases where valid quality or cost scores cannot be produced, we suggest allowing participants the opportunity to supplement with available IA or PI scores to avoid being entirely unscored.

Complex Patient Scoring Adjustments

We support the inclusion of a complex patient scoring adjustment based on HCC scores and dual-eligible proportion, as it acknowledges the real-world challenge of caring for patients with significant medical and social risk factors. However, we note that the adjustment applies only at the final score level and does not influence individual performance categories, such as cost or quality. As a result, the scoring still risks penalizing clinicians whose quality or cost performance is negatively impacted by patient complexity.

HCC and dual-eligible status may not fully capture medical or social complexity. For example, patients with HF and multiple co-morbidities (e.g., cognitive impairment, frailty) may not have high HCC scores if diagnoses are not fully coded or incomplete. High-volume or hospital-based clinicians where hospital coders, not clinicians, determine how conditions are documented could be prone to incomplete documentation.

The proposed threshold of limiting the bonus only to those above the median may exclude clinicians serving moderately complex populations who may also experience significant care management burdens. We encourage CMS to improve transparency by clearly reporting how the adjustment is

calculated and how clinicians can reduce risk. Given the high 50% weight assigned to cost performance in the ASM, we recommend evaluating whether the 10-point cap on this adjustment is sufficient to meaningfully offset penalties for those treating disproportionately high-risk populations.

Small Practice Scoring Adjustments

We support the proposed 10-point bonus for small practices and 15-point bonus for solo practitioners. This simple, transparent approach appropriately is a fair compromise for known disparities in reporting infrastructure, staffing, and capacity. Many rural cardiologists operate in small settings and this adjustment may be essential to keep them participating in the ASM. This is important given the high-cost performance weight (50%) and technological demands of reporting MVP-aligned quality measures. We understand CMS's rationale for not including a rural adjustment on top of the small practice bonus but recommend CMS monitor performance by geography in the early years of ASM to ensure rural practices are not disproportionately harmed.

Based on the 2023PY PUF data released earlier this year, solo practitioners had the lowest mean score (53.64) and the highest average penalty (-2.89%). They are also less likely to report or engage in MVPs and thus may be disproportionately penalized under a mandatory model like ASM. CMS should conduct impact modeling by practice size and location to avoid exacerbating disparities.

Final Score Calculation

Concentrating 100% of the base score in Quality and Cost for a relatively small heart-failure panel, then layering mostly negative "adjustments," creates volatility and departs from clinicians' MIPS/MVP experience. **The College suggests phasing in the Cost weight and applying a reasonable year-over-year glidepath to limit large swings; treating Improvement Activities and Promoting Interoperability as positive credit only (not deductions); adding reliability and volume safeguards that reweight when measure reliability is low or case counts are small (or allow TIN-level scoring); and publishing clear, detailed formulas, benchmarks, and reference populations. Finally, a pilot year is needed so clinicians can validate attribution and scoring before any payment risk applies.**

Proposed ASM Payment Approach

Payment Approach

The College has identified potential issues with the proposed ASM payment approach. While several payment determining factors resemble those used in MIPS or other value-based purchasing programs that clinicians may already be familiar with, we have also identified significant differences that could hinder participants' ability to financially succeed in the model.

We believe that all ACC members who would be assigned to participate in the model can improve quality of care within the model and should be rewarded for improvements. Our membership prioritizes collaboration, often contributing their time, research, scholarship, and clinical insights to

ensure all clinicians have the needed resources to provide optimal cardiovascular care. Given this priority, the College questions whether using a care model to drive competition between providers will result in nationwide collective care improvements for Medicare patients. This is especially troubling if the model financially punishes clinicians who are demonstrating improved care and saved cost, yet not realizing financial rewards due to competition built into the model. The ACC encourages CMS to consider potential unintended consequences such as clinician burnout, shifts of employment type, adverse patient selection, and decreased specialist collaboration during initial rulemaking rather than solely in a review period when unintended consequences might already have occurred.

Comparison of ASM Participant Performance

The ACC is supportive of the proposal that incentive pools and scoring should be distinct and separate for the Heart Failure and Lower Back Pain cohort. Comparisons made across two completely different chronic conditions would do little to inform participants or CMS about best practices that could lead to success in the model, savings for CMS, and improved patient care. The College notes that even within the HF cohort, fair comparison of participants is challenging.

The model should ensure fair attribution and reasonable risk. As was demonstrated in the cost measure testing, the 20 minimum case threshold should be sufficient for reliability. As we previously noted, while 20 episodes may be a reasonable starting point, it may not adequately reflect the variability in cardiologists' practice patterns across rural, urban, or hospital-based settings. Risk adjustment should include protection from outliers and ensure that there is a limited band for risk and a cap on the amount, so one atypical case does not disproportionately affect payment. Clinicians should have clear attribution rules, the ability to review/appeal patient panels, and transparent performance reports.

The ACC is troubled that cardiologists in the ASM will not have an established score that could be achieved to prevent the financial penalty. A performance threshold as utilized in MIPS to avoid penalty is needed in the ASM. The proposed approach does not reward high value care unless other clinicians in the cohort provide less high value care. A cardiologist earning top scores in quality, and no loss of points in improvement activities and promoting interoperability can only improve by "winning" at cost. A race for the bottom of cost could jeopardize care. A clinician who excelled in other areas but has a high-cost score should not incur a financial penalty in the ASM if they achieved a set performance goal built into the model.

Participants are likely to struggle in the ASM's proposed "tournament style" in which clinicians are competing against one another toward an unknown goal. A potential solution would be to use the median determined by the exchange function during the previous model year to compare participants. With this established and published median, participants would know clearly at which score they are ensured of no financial penalty.

ASM Risk Level

The ACC strongly recommends that ASM clinicians have the option for a first performance year in which a clinician can opt for a track with no downside financial risk, and corresponding lesser up-side potential. Such glide paths have been used in other CMMI models and have served to increase participant understanding of the model and its nuances. The ACC believes this is particularly important in the ASM, a mandatory model which is likely to include some clinicians with very little awareness and experience in care model participation. The ACC opposes the proposed increases to ASM risk levels in model years 3-5. The College believes risk level is another area where it is appropriate to mirror the MIPS program, with maximum penalties to clinicians of 9% in any model year. Later model years with proposed risk levels of 10-12% applied to the entirety of a participant's Part B claim is extreme and untested in other programs, even programs with voluntary participation. The ACC supports a steady risk level of 9% throughout the ASM test period.

ASM Redistribution Percentage

The ACC strongly opposes the proposed use of an ASM redistribution pool which would withhold a proposed 15% of the pool rather than distributing the pool in its entirety back to clinicians at risk in the model. As proposed, the collective of cardiologists in the model will experience a 1.3% decrease in their ASM payment adjustments in the model's first payment year with increases to as high as 1.8% if, as proposed, risk levels increase by the final model year. While clinicians could succeed in the model, as proposed this redistribution pool puts randomly selected mandatory participants at additional and unjust financial risk to build in cost savings for CMS. Like the MIPS program, the ASM should be budget neutral. We believe cardiologists in the model will succeed in reducing the cost of care to their HF patients and this will produce savings for CMS. Building CMS cost savings into the ASM by withholding any percentage from redistribution to participants is not an appropriate test of the model and its success.

Exchange Function

As CMS calculates ASM payment adjustments for participants, ACC suggests a cautious approach. As MIPS is the QPP program most familiar to cardiologists, CMS should utilize similar functions and calculation of payments in the ASM, a model largely built on MIPS structure. The College sees value in the use of a linear exchange function, not only for its familiarity but in the protection it could provide participants. The College opposes the use of a logistic exchange function for its lack of familiarity and for its selection for the purpose of pushing towards the extremes of payment adjustments in the model. As noted above, the College questions whether driving competition and high percentage payment adjustments will inherently improve care for the whole of Medicare HF patients. Accessible cardiovascular care is vital. The ASM should avoid driving a large number of the highest allowable financial penalties which might shutter practices, spur early clinician retirement, exacerbate clinician burnout or drive clinicians outside of rural settings and jeopardize this access.

Proposed Timely Error Notice Process

In regard to the notification of payment adjustment, we appreciate that CMS has a process for model participants to review their performance and appeal errors in data or calculations used to determine payments. The College believes that the 60-day window of the Quality Payment Program allotted for participants in the MIPS program should be mirrored in the ASM. Not only has a 60-day review timeline been standardized in MIPS, a 30-day window could inhibit a participant's thorough review.

Proposed Waivers of Medicare Program Requirements

The College appreciates CMS's consideration of waivers to facilitate success for participants in the ASM. We strongly support waiving MIPS participation for ASM participants for relieving reporting burden and allowing participants in the ASM to adjust focus to new reporting requirements. We believe this waiver should apply to any ASM participant identified for a model year, throughout the full course of any year they are identified as ASM participants.

The College is equally supportive of the proposed telehealth waivers which will help participants provide timely and efficient care to their patients. We believe these waivers are likely to help participants provide quality and cost-effective care to patients. Additionally, we recognize telehealth often enables access and care in a location patients prefer and believe this waiver could help achieve the College and agency's shared goal of prioritizing patient experience. The College notes that should expansion of telehealth services for Medicare patients be enacted by federal law, ASM participants' telehealth waiver should be no less restrictive than allowed by law.

We are generally supportive of the proposed ASM beneficiary incentives as the College believes that patients who take an active role in monitoring their HF benefit. Providing access to patient monitoring tools which enable this could drive improved results in the ASM. The College encourages CMS to reconsider the structure of this proposed beneficiary incentive. Clinician financed incentives could be problematic given varying practice resources and accessibility. We propose that all eligible patients in the ASM be provided with Medicare supplied blood pressure cuff, weight scales and other risk measurement tools to enable their active role in self-monitoring HF. This equipment can potentially reduce the need for emergent care and hospital admission. Additionally, the ACC notes that previous models, such as the Enhancing Oncology Model, provide additional payments to specialists to support enhanced services. If specialists are to supply beneficiary incentives, CMS financial support for beneficiary incentives should be included.

Updates to the Quality Payment Program

MVP Participant Definition and Small Group Option

We appreciate CMS's recognition of the limitations in using Medicare Part B claims data to determine whether a group practice qualifies as a single-specialty or multispecialty group. The specialty codes on claims data may reflect provider credentials or administrative classifications rather

than the actual clinical focus of care delivered within a group. This is particularly true for multidisciplinary cardiovascular care teams that may include internists, cardiologists, nurse practitioners, and physician assistants that work in the same service line (e.g., heart failure, structural heart). Labeling groups 'multispecialty' based only on taxonomy may not reflect how care is actually delivered and thereby trigger unnecessary subgroup reporting that fragments care and adds administrative burden.

We support CMS's proposal not to use claims alone and to introduce a self-attestation process as part of MVP registration, allowing practices to designate themselves as either a single-specialty group or a multispecialty group that meets the definition of a small practice. This approach offers more flexibility and acknowledges the realities of care delivery for integrated teams. However, we encourage CMS to clearly define what constitutes a "single focus of care" to prevent confusion or inconsistent interpretation across groups. Including examples in future guidance would help ensure alignment and reduce ambiguity during registration. We also support the proposed exemption from subgroup reporting for multispecialty groups with 15 or fewer clinicians. Recognizing the resource limitations of small practices is important to maintaining equitable access to MVP participation.

Core Elements RFI

The proposed Core Elements policy appears to be a mechanism toward enabling more meaningful and standardized performance comparisons across clinicians. However, the proposal mirrors past approaches from the PQRS that were ultimately unsuccessful. In that program, mandatory cross-cutting measures presented challenges and were eventually abandoned. That was in part because it did not reflect the diversity of clinical practice, introduced unnecessary burden, and limited meaningful clinician choice. While we appreciate CMS's intent to improve comparability and transparency, strict core measure requirements will limit the flexibility that MVPs were originally designed to promote. This policy could disincentivize participation in MVPs and ultimately undermine the goal of moving clinicians away from traditional MIPS. While standardization is a worthy goal, Core Elements should not reintroduce the same burdensome "box-checking" structure that MVPs were designed to improve upon.

The current MVP framework is designed with rigid measure requirements, which can create misalignment. For instance, the "Advancing Care for Heart Disease" MVP includes cost measures specific to PCI or device implant procedures, but lacks corresponding MIPS quality measures (e.g., those assessing PCI outcomes, ablation safety, or structural heart interventions). As a result, subspecialists may be evaluated on condition-level cost performance without having access to relevant or actionable quality measures. Adding mandatory Core Elements to this imbalance could further add to clinician burden and lead to inappropriate comparisons.

If CMS were to proceed with this proposal, the ACC recommends that any required Core Elements are broadly applicable across subspecialties or allow clinicians to attest that none are relevant in their practice context. Additionally, the proportion of mandatory Core Elements should be limited to no more than 20–25% of the MVP's total quality measure set, or alternatively, allow for a slightly higher number (e.g., 2–3) in certain MVPs to reflect the field's complexity. Core Element options across

multiple collection types (e.g., eCQMs, MIPS CQM, and QCDR) should be provided to avoid forcing clinicians into new and potentially burdensome reporting mechanisms that are misaligned with their existing facility or practice infrastructure. Registry participation should be recognized as a valid reporting option under MVPs, as it provides clinically rich data that can enhance measure accuracy and relevance. CMS should ensure that clinicians have multiple options for fulfilling reporting requirements.

Medicare Procedural Codes RFI

The College is concerned that mandatory MVP assignment based on procedural billing codes conflicts with the MVP program's stated goals, which is less burden and more relevance through choice. Clinicians were encouraged to move to MVPs because they could select measure sets that fit their practice. Forcing assignment, especially using claims that may be up to two years old and not reflective of current roles or service-line changes, risks misattribution and disengagement. CMS itself notes that requiring a specific MVP "would limit clinicians' ability to choose," yet frames it as a way to boost participation.

This approach is especially problematic in cardiovascular care, where many subspecialties (EP, interventional, heart failure, general cardiology) bill overlapping CPT/E/M codes. Procedural codes alone won't reliably distinguish non-procedural, population-health roles (e.g., general cardiology, heart-failure management) or clinicians who do few procedures but provide high-value longitudinal care. In short, billing codes do not consistently capture clinical intent, team-based delivery, or subspecialty distinctions needed for fair comparisons.

If CMS uses claims to suggest MVPs, we recommend pairing procedural codes with 1) diagnosis (ICD-10) groupings that reflect clinical focus (e.g., heart failure, ischemic disease), 2) E/M visit volume and the share of total visits/allowed charges in that area, and 3) place of service (e.g., outpatient clinic vs. cath lab). This better reflects scopes of care for clinicians whose work is primarily evaluation/management, longitudinal disease management, and care coordination. One other specialty-specific consideration is that cardio-oncology and cardio-obstetrics are growing areas with few or no distinctive procedural codes. CMS should recognize these through diagnosis/E/M patterns and permit clinicians to select the most appropriate MVP when available codes are insufficient.

If CMS moves forward with a claims-based MVP attribution model, we encourage alignment with frameworks like the proposed ASM, which allow clinicians to validate or appeal their assignment. This is essential to ensure that performance measurement reflects clinicians' actual scope of work and maintains clinical relevance. For volume thresholds, a 20–25 case minimum is reasonable if it also examines a "share-of-practice test" (e.g., ≥20–30% of E/M visits or allowed charges in that domain) to prevent mislabeling clinicians whose involvement is minimal.

Toward Digital Quality Measurement in CMS Quality Programs RFI

As part of the proposed rule, CMS seeks comments on the anticipated approach to the use of Health Level Seven® (HL7®) Fast Healthcare Interoperability Resources® (FHIR®) in electronic clinical quality measure (eCQM) reporting. The College agrees with CMS that having immediate access to electronic health information, in near real-time, supports quality measurement efforts, provides the ability to use these data for patient care considerations, and may lead to improved clinical outcomes. It is important to note that while there has been considerable progress in the development and utilization of FHIR-based application programming interfaces (API) to assist with the standardized submission of quality reporting data elements, **there is still considerable work to be done. As this process continues, the ACC stands ready to work with CMS and other regulatory agencies to help progress standardization and interoperability efforts.**

In previous requests for information and rulemaking, CMS stated the intent to transition to full digital quality measurement by 2025. **While the College was encouraged by the urgency and dedication to evolving how digital quality measurement takes place, the ACC expressed the need for more measured approaches that take into consideration the reality of current and near-term measure development and reporting processes.** As CMS notes in the RFI, multiple standards are currently used to report electronic clinical quality measures (eCQMs, making it a challenging and burdensome process.

Previous experience partnering with the Chesapeake Regional Information System for our Patients (CRISP) to build upon known standards and systems to allow healthcare organizations which partner with the National Cardiovascular Disease Registries (NCDR) has helped inform the College about the resources required to successfully crosswalk quality measures. We are aware that at least one cardiology-related eCQM, such *as Statin Therapy for the Prevention and Treatment of Cardiovascular Disease* (CMS #347), has been translated into a FHIR-based specification.

It is notable that approximately half of the top 10 measures most frequently reported from the cardiology MIPS measure set are eCQMs, including measures such as #236 (Controlling High Blood Pressure) and #130 (Documentation of Current Medications). While this demonstrates meaningful progress in digital measure adoption, it still falls short of CMS's earlier stated goal of achieving 100% eCQM reporting by 2025. The College believes that many cardiology measures used or stewarded by cardiologists are still in QDM or non-FHIR formats. This suggests that significant barriers remain, particularly around data capture, EHR integration, and workflow alignment, which must be addressed before broader adoption is feasible. **As CMS continues to prepare for the transition to digital quality measurement, it is imperative any policies provide sufficient time, resources, and technical assistance to quality measurement developers such as the ACC and data sources such as the NCDR to help with the transition.**

In the request for information, CMS considers the requirement that all measures proposed for addition to CMS programs be specified in FHIR. While the ACC appreciates the commitment to the development of standardized measures, the current reality is measures utilized by the entire cardiovascular team exist in multiple standards, some of which are commonly used and others of

which are proprietary standards developed in close consultation with hospitals and other reporting sites. It will take extensive time and resources to make these measures FHIR-based.
As the experience with the CMS Innovation Center's Enhancing Oncology Model has shown, it can take years from development to reporting at the site of care for specialty clinical data elements. As HHS moves towards the implementation of these measures, CMS should assess why full transition to eCQMs has not occurred as anticipated and work with medical societies to develop a more realistic and flexible pathway for increasing digital measure use without disrupting high-value reporting mechanisms already in place.

CMS also asks for input on the timeline for transitioning to FHIR-based reporting for clinical measures. CMS indicates they are considering proposing a transition period during which healthcare providers may report using either QDM- or FHIR-based eCQMs and would consider a two-year reporting option before any mandated reporting requirements. **While the College appreciates the intent behind a transition period and a minimum of 24 months from the effective date of a FHIR-based eCQM reporting option using ONC Health IT Certification Program criteria to support quality program submission and provide sufficient time for implementation, if CMS were to move forward with a proposal for CY 2027 and a mandated reporting period starting in CY 2029, the College and similar entities would currently have difficulty meeting this timeline.**

As previously stated, the College lacks the resources to fully crosswalk measures to FHIR-based standards and a lack of definitive direction from agencies prevents the ACC from investing necessary resources in this transition. **Instead, CMS should provide medical societies, clinical data registries, and measure stewards with specific direction and sufficient warning before implementing major changes.** After sufficient warning, CMS could proceed with a transition period allowing either QDM or FHIR-based reporting, allowing for additional testing and transition time. This will allow all necessary stakeholders to have a clearer understanding of the requirements and specifications they must build around and allow providers the time to prepare for a new reporting paradigm. An example of this proposed timeline could be CMS announcing intent to transition to FHIR-based reporting by CY 2032 in the CY 2027 rulemaking cycle, with a two-year dual reporting period for reporting years 2030 and 2031.

CMS should also explore ways to reduce the complexity of the submission process, including offering centralized platforms or leveraging medical society registries that already collect high-quality data. In many cases, registries and medical societies can offer more accurate, clinically nuanced data that reflects the complexity of care. Many data elements used in current eCQMs are either not routinely captured in structured EHR fields or are captured inconsistently across systems. Specific clinical findings, procedure indications, and shared decision-making elements are often documented in free text or within registries, rather than in discrete EHR fields that align with QI-Core profiles. Registries, however, are nimble and adaptable and can quickly add fields to capture additional data. **CMS should permit the use of validated registry or third-party vendor data where appropriate, especially when it enhances the accuracy and utility of performance measurement.**

Additionally, attribution logic can be particularly challenging to represent accurately in FHIR, especially for measures that span multiple providers or care settings. Without standardization of these data inputs across EHR vendors and sufficient time for mapping, validation, and workflow integration, the transition could place a significant burden on clinicians and health IT teams. **As CMS considers this shift, we urge close collaboration with medical societies and registries to identify which measures are most feasible to convert and to ensure that any transition maintains clinical accuracy and usability.**

APM Performance Pathway

The ACC supports CMS's continued development of the APP Plus measure set and the goal of advancing patient-centered, equitable care. However, any measures added to the APP and APP Plus quality measure sets should be relevant and actionable for the clinicians required to report them. Many of the proposed additions, such as those from the Adult Universal Foundation set, may be more appropriate for primary care providers than for specialists like cardiologists.

As the APP Plus set expands in each performance year, we are concerned about increased reporting burden, particularly in multispecialty ACOs where specialists may be held accountable for measures unrelated to their scope of practice. CMS should provide clear guidance on attribution methodology and consider flexible reporting options that allow subspecialists to be held accountable for the measures most aligned with their clinical role.

Quality Measures

We urge CMS to expand, rather than limit, the number of measures available in MIPS to ensure alignment with episode-based cost measures, alternative payment models, and other quality programs. Without additional measures, clinicians will have limited opportunities to demonstrate meaningful performance, which undermines both patient-facing transparency and the successful transition to MVPs.

We also strongly encourage CMS to revive and promote the Qualified Clinical Data Registry (QCDR) pathway, as envisioned under MACRA. QCDRs were intended to provide a separate avenue for measure review and to capture outcomes most relevant to specialty care. However, CMS's recent exclusion of QCDR measures for MIPS and MVPs has led to a decline in registry participation. This trend is concerning, given the unique value of registries in capturing comprehensive data across settings and conditions, supporting quality improvement, guideline development, and research, and facilitating a transition toward digital quality measurement.

By actively incorporating specialty-led QCDR measures into MIPS and MVPs, CMS can preserve the intent of MACRA, strengthen specialty engagement, and ensure that the program continues to evolve in a way that reflects the realities of clinical practice.

Measures Proposed for Removal from the Cardiology Specialty Measure Set

1. *Measure #322 – Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Preoperative Evaluation in Low-Risk Surgery Patients*

While we recognize CMS's rationale for proposing removal of Measure #322 due to topped-out status and a near-zero mean performance rate, we caution against eliminating one of the only cardiology-specific efficiency measures currently in the specialty set. Cardiac imaging remains a critical issue in practice and policy, and the measure continues to serve as an important signal to clinicians, health systems, and payers that appropriate use is being tracked. However, we do not oppose retirement if CMS pairs it with a clear replacement strategy so imaging stewardship remains visible in MIPS for cardiology.

A better replacement would be a broader imaging overuse measure spanning echocardiography, nuclear stress testing, and coronary CTA, focused only on clearly low-value scenarios. To reflect real practice, pair procedure codes with diagnosis groupings, E/M visit patterns, and place of service so the measure captures the clinical purpose, not just test volume, and works across settings. In addition, CMS could utilize clinical decision support (CDS) as many EHRs already include prompts that have reduced inappropriate pre-op testing. CMS could award Improvement Activity credit for CDS use and for feedback to ordering clinicians. Claims data could then be used to flag high-outlier sites for targeted outreach.

2. *Measure #487 – Screening for Social Drivers of Health (SDOH)*

Social risk factors such as food insecurity and housing instability are known contributors to cardiovascular health disparities. In an era of increasing focus on health equity and SDOH, we believe it is not the right time to remove this measure from the specialty set. Many cardiology practices, particularly in ACOs or integrated care models, are beginning to embed SDOH screening into routine workflows. ACOs operate under value-based payment arrangements, which incentivize them to improve patient outcomes and control costs. Addressing SDOH is seen to achieve both. Removing the measure may discourage continued advancement in this area. If CMS proceeds with removal from the cardiology set, the ACC urges its retention in primary care-aligned or multispecialty MVPs to ensure continued attention to social risk factors to improve outcomes across specialties.

Proposed Quality Measure Updates

1. *Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control)*

We support CMS's proposed updates to the IVD All-or-None Outcome Measure to align with the latest clinical guidelines for high-risk cardiovascular patients. The revisions, particularly the tighter blood pressure target (≤130/80 mmHg) and specification of high-intensity statin use, appropriately reflect evidence-based goals from the 2023 AHA/ACC/ACCP/ASPC/NLA/PCNA Guideline for the Management of Patients with Chronic Coronary Disease.

To strengthen this and similar measures, CMS should consider the burden imposed by an "all-or-none" measure, where even one unmet criterion, such as a missed blood pressure reading or incomplete documentation of tobacco use, can disqualify the entire encounter. This approach may unfairly penalize clinicians for factors not necessarily tied to care quality, especially for those serving high-risk or underserved populations. Alternative approaches to incentivize performance without penalty could include scoring individual components or using a stratified composite model (e.g., patient refusal of high-intensity statins or inconsistent blood pressure follow-up). If the measure could be modified, we would also propose an average BP reading over the last 3 months vs. last BP reading as is proposed for HEDIS measures.

Appropriate attribution is essential when certain activities such as BP monitoring or tobacco cessation counseling may be primarily managed by primary care providers. In multispecialty or integrated settings, CMS should consider shared accountability across care teams to reflect how care is delivered in practice. We appreciate CMS's effort to modernize the measure's clinical alignment but recommend ongoing monitoring of unintended consequences, particularly on performance in high-SDOH-burden populations or smaller cardiology practices.

2. *Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (MCC)*

We recommend that CMS consider the effects of the proposal to remove the QP exclusion from the Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (MCC) measure. Including patients assigned to QP clinicians, who are exempt from MIPS reporting, may lead to inappropriate comparisons and benchmarking distortions. This change risks holding MIPS participants accountable for outcomes influenced by patients not under their care or who are managed under different care models. This could undermine efforts to clearly distinguish between incentive paths and make the measure less actionable for MIPS participants.

It is also important to address whether clinicians involved in both APM contracts and MIPS subgroup reporting could face duplicative accountability or conflicting incentives. In cardiovascular care, patients with multiple chronic conditions are commonly managed by both primary care providers and specialists. CMS should take this into account by refining attribution methods to reflect shared care across specialties, distinguishing between preventable and non-preventable admissions, and ensuring transparent risk adjustment, especially for cardiologists treating complex patients with heart failure, chronic kidney disease, and arrhythmias. Until QPs are subject to a similar attribution mechanism, we recommend retaining the QP exclusion to retain the integrity and fairness of the measure.

Cost Performance Category Updates

CMS is not proposing to adopt any new measures for the CY 2026 performance period/2028 MIPS payment year and is not proposing to remove any measures for the CY 2026 performance

period/2028 MIPS payment year. The College thanks CMS for providing MIPS eligible clinicians, eligible hospitals, and CAHs with stability in the MIPS program, specifically the Cost Performance Category, so they can continue to gather experience and monitor progress in terms of cost performance.

Two Year Informational Feedback Period

The ACC supports the proposal to adopt a two-year informational-only feedback period for new MIPS cost measures, beginning with the CY 2026 performance period/2028 MIPS payment year. We agree that this approach is a reasonable and much-needed step toward increasing transparency, clinician engagement, and performance improvement in the MIPS Cost category. Specialties like cardiology often face complex and confusing attribution and benchmarking methodologies. For measures involving complex attribution models, high-cost services, or significant changes to data systems, CMS should allow an extended feedback period of up to three years.

We commend CMS for recognizing the concerns raised by clinicians and specialty societies around the lack of timely, actionable data on cost measure attribution and scoring. Providing confidential, informational-only feedback during the initial two years of measure implementation is an improvement in terms of helping clinicians understand the scope and methodology of new measures before those scores affect payment. Detailed reports explaining which patients and services were attributed, how costs were calculated, and how their performance compares to peers will improve transparency.

Clarification is needed on how scoring will work for MVPs that include cost measures still in their feedback phase. CMS should ensure that clinicians are not penalized or confused by interim scoring policies and that MVP participation remains fair and transparent. Lastly, we strongly support CMS's proposal to delay public reporting until after the feedback period concludes. Early publication of performance data could be misleading and damage professional reputation without offering real quality improvement benefits.

Total Per Capita Cost Measure Changes

We support the proposed refinements to TPCC that sharpen its focus on longitudinal, person-focused cost accountability. In cardiovascular practice, cardiologists typically contribute within multidisciplinary, team-based care rather than serving in a central role for longitudinal care for most Medicare beneficiaries; attribution should reflect that role.

The proposed revisions to require both candidate attribution services 1) to be performed by clinicians from the same group, and 2), provided only by clinicians not excluded from the specialty exclusion criteria, are a welcome change. These will reduce the likelihood of fragmented or inappropriate attribution to specialists who are not responsible for longitudinal care management. We also support the proposed exclusion of APPs from TPCC attribution when they practice in specialty-focused clinician groups (e.g., cardiology-only groups where all physicians are excluded

based on specialty criteria). This change appropriately acknowledges that APPs in these settings may be delivering subspecialty rather than primary care services.

Based on the proposed specialty eligibility list, general cardiologists (Code 06) and advanced heart failure/transplant cardiologists (Code C7) would remain included in TPCC attribution, while interventional cardiologists (Code C3) would be excluded. This distinction creates inconsistencies in how cardiology subspecialists may be held accountable under the measure, especially within multispecialty or subspecialty cardiology groups. In many cases, these clinicians operate as part of an integrated cardiovascular team, and attribution to one subspecialist versus another based on coding could misrepresent the longitudinal care relationship. All cardiology subspecialties, including interventional cardiology, should be included in the program.

The College recommends that CMS reexamine whether attribution to cardiology specialties in TPCC is appropriate, given the intent of the measure is to reflect primary care-driven cost accountability. Cardiologists often provide consultative, episodic, or co-managed care, and are rarely the sole source of primary care services. If cardiologists remain eligible for attribution under TPCC, we strongly urge CMS to clearly define when attribution is appropriate (e.g., in the rare cases a cardiologist is acting as a primary care provider) and provide transparency in attribution logic at the clinician and TIN levels. The measure should also be intuitive and transparent from a patient perspective, enabling patients to understand how their care and associated costs are being assessed.

General Cost Measures Comments

The ACC conducted an analysis using data provided by the 2023PY PUF released earlier in 2025, filtering down to the six cardiovascular clinical categories: cardiology, adult congenital heart disease, advanced heart failure and transplant, cardiac surgery, EP, and Interventional. We have included a table summarizing the cost measures to which cardiologists were attributed in the 2023 MIPS performance year. As shown in the table, cardiologists were attributed to a wide array of episode-based cost measures, including several that are unrelated to their scope of practice. While it is appropriate to see attribution to cardiology-relevant measures such as Elective Outpatient PCI, STEMI with PCI, and Non-Emergent CABG, the data also show attribution to procedures that fall outside the specialty's clinical purview, such as knee arthroplasty, colon and rectal resection, cataract removal, melanoma resection, and even lumpectomy.

Measure Name	Reporters	Average Points
MSPB	8,896	7.64
TPCC	8,306	6.31
Diabetes	6,590	4.75
Sepsis	6,506	8.69
Elective Outpatient Percutaneous Coronary Intervention (PCI)	**4,417**	**6.66**
Revasc for Lower Extremity Chronic Critical Limb Ischemia	3,989	6.91

Acute Exacerbation of Chronic Obstructive Pulmonary Disease (COPD)	3,743	4.81
Inpt COPD Exacerbation	3,528	7.36
Intracranial Hemorrhage or Cerebral Infarction	2,819	7.54
Non-Emergent Coronary Artery Bypass Graft (CABG)	**2,807**	**7.72**
Screening/Surveillance Colonoscopy	2,431	6.98
Renal or Ureteral Stone Surgical Tx	2,387	7.36
Lower Gastro Hemorrhage	2,380	7.68
Lumpectomy, Partial Mastectomy, Simple Mastectomy	2,335	7.71
Femoral or Inguinal Hernia Repair	2,187	6.82
Knee Arthroplasty	2,086	6.84
Lumbar Spine Fusion for Degenerative Disease	2,021	7.61
Colon and Rectal Resection	1,894	7.69
Elective Primary Hip Arthroplasty	1,893	6.97
Hemodialysis Access Creation	1,779	7.13
ST-Elevation Myocardial Infarction (STEMI) with PCI	**1,759**	**7.30**
Melanoma Resection	1,544	7.10
Acute Kidney Injury Requiring New Inpatient Dialysis	1,319	8.09
Routine Cataract Removal with IOL Implantation	1,202	7.65

Attribution to non-cardiology services in these cases likely reflects flaws in the cost measure assignment algorithm. This may affect the credibility of the cost performance category by introducing potential inaccuracies in data interpretation and unintended consequences for specialists. To maintain confidence in the program, we encourage CMS to enhance transparency in attribution logic and ensure that cost measures are applied only when the clinician's role is both meaningful and clinically appropriate.

Conversely, cardiology-specific cost measures such as Elective Outpatient PCI (4,417 reporters), Non-Emergent CABG (2,807), and STEMI with PCI (1,759) had significantly lower reporting volumes, even though they are much more clinically relevant to the specialty. This discrepancy suggests that current attribution methods may be over-inclusive in assigning cardiologists to general measures while under-attributing them to more relevant, specialty-specific episodes.

Even among relevant cardiology measures like STEMI with PCI (average score of 7.30) and CABG (7.72), performance remains modest, raising questions about risk adjustment methodology and the degree to which physicians can control total episode costs. CMS should ensure that cost measures for cardiovascular conditions reflect the realities of team-based care and properly account for hospital and post-acute drivers of spending. Overall, CMS should refine its attribution methodology to better align cardiologists with specialty-relevant episodes, avoid holding them accountable for non-cardiac procedures, and improve the accuracy, transparency, and clinical validity of cost performance measurement in MIPS.

Improvement Activities Performance Category

Proposals to Adopt New Improvement Activities Beginning with the CY 2026 Performance Period/2028 MIPS Payment Year

CMS proposes to adopt a new improvement activity, IA_PSPA_XX, titled "Patient Safety Use of Artificial Intelligence" for the CY 2026 Performance Period/ 2028 MIPS Payment Year. This new activity would develop a new data-collection field within patient safety reporting systems for AI-attributable events, which would include both actual harm as well as near misses. When an event is identified, a process to identify the cause and plan for future mitigation is documented. AI-attributable events are defined broadly to include not only automated or semi-automated devices, but any electronic tool that is being used to support clinical decision making.

As AI is increasingly utilized in clinical practice to help with decision-making and reducing administrative burdens, it is important to incentivize the study of the impact of AI, particularly the potential for harm to patients. The College supports the development of this activity.

Promoting Interoperability Performance Category

Proposal to Modify the Security Risk Analysis Measure

CMS proposes to modify the existing Security Risk Analysis measure to require eligible hospitals and CAHs to attest "yes" to having conducted security risk management as required under the HIPAA Security Rule implementation specification for risk management. Currently, the Security Risk Analysis measure only requires eligible hospitals and CAHs to attest "yes" or "no" as to whether they have conducted or reviewed a security risk analysis.

The proposed changes to this measure would align with the proposed modifications to the HIPAA Security Rule in RIN 0945-AA22 *HIPAA Security Rule to Strengthen the Cybersecurity of Electronic Protected Health Information*. Under that proposed rule, CMS clarifies the actions, such as deploying safeguards, that would be required to meet the HIPAA Privacy Rule requirements. Likewise, modifying this measure would require eligible hospitals or CAHs to conduct a security risk analysis to receive credit. **The College supports efforts by CMS to better guard protected patient health information (PHI), including modifying the Security Risk Analysis measure.**

Proposal to Modify the High Priority Practices Safety Assurance Factors for EHR Resilience (SAFER) Guide Measure

CMS proposes to modify the SAFER Guides measure by requiring eligible hospitals and CAHs to attest "yes" to completing an annual self-assessment using all eight 2025 SAFER Guides to be considered a meaningful EHR user, beginning with the EHR reporting period in CY 2026. The College has supported efforts by HHS to improve cybersecurity, including creating the SAFER Guides measure. **The ACC thanks CMS for working to update the measure to align with new**

SAFER guides that focus on the highest risk, most commonly occurring issues that can be addressed through technology or practice changes to build system resilience. By doing so, HHS can continue to incentivize the implementation of best practices that increase cybersecurity preparedness.

Public Health and Clinical Data Exchange Objective: Proposal to Adopt the Public Health Reporting Using the Trusted Exchange Framework and Common Agreement (TEFCA) Measure as an Optional Bonus Measure Beginning with the CY 2026 Performance Period/2028 MIPS Payment Year

CMS proposes adding an optional bonus measure under the Public Health and Clinical Data Exchange objective for health information exchange with a public health agency (PHA) that occurs using TEFCA. Under this measure, an eligible hospital or CAH that signs the Framework Agreement, meets their eligibility requirements, and submits health information using TEFCA and is in active engagement with a public health agency would be eligible for the bonus points.
While the College supports any efforts to incentivize continued adoption of interoperability capabilities such as TEFCA, the College is concerned that the elimination of entities that are in pre-production or validation (Option 1 under the current measure) will reduce the applicability of this measure. If the goal is to continue to incentivize signatories to the Framework Agreement and encourage electronic health information exchange via TEFCA to PHAs, CMS should continue to allow for Option 1 eligible hospitals and CAHs to claim this measure.

Currently, TEFCA only has 9 designated Qualified Health Information Network® (QHINs™) with another currently onboarding. While these QHINs do provide access to vast amounts of information electronically and cover tens of millions of patients, TEFCA is still in its infancy and signatory participation is somewhat limited, especially among smaller or eligible rural hospitals and CAHs. These entities may still be examining participation as TEFCA adoption grows and allowing them to claim the measure while in pre-production or validation can help to continue to incentivize this adoption process. **The College encourages CMS to reconsider removing Option 1 from the Public Health Reporting Using TEFCA measure until TEFCA adoption reaches a mature, steady state.**

Proposal to Adopt Measure Suppression Policy for the MIPS Promoting Interoperability Performance Category Beginning with the CY 2026 Performance Period/2028 MIPS Payment Year and for the Medicare Promoting Interoperability Program for Eligible Hospitals and Critical Access Hospitals (CAHs) Beginning with the EHR Reporting Period in CY 2026

CMS proposes to adopt a measure suppression policy to permit CMS to exclude a measure from scoring or the determination of a meaningful EHR user for an applicable performance period/MIPS payment year or EHR reporting period in an applicable CY. According to CMS, such a measure suppression policy would allow CMS to exclude a measure from scoring due to circumstances that impede the effective measurement of a measure within the measure's applicable objective or to exclude such a measure from the determination of a meaningful EHR user for measures that are not scored. CMS has previously proposed measure suppression policies for the MIPS quality performance and cost performance categories.

Like other suppression policies for MIPS performance categories, CMS would determine whether certain circumstances exist warranting suppression of a measure within the MIPS Promoting Interoperability performance category or Medicare Promoting Interoperability Program based on CMS's consideration of one or more factors. For any CMS measures determines must be suppressed based on one of more of the factors identified, CMS would notify MIPS eligible clinicians, eligible hospitals, and CAHs of the suppression via existing communication channels.

The ACC thanks CMS for proposing to adopt and codify a measure suppression policy for the MIPS Promoting Interoperability performance category beginning with the CY 2026 performance period/2028 MIPS payment year and supports the development of this policy.

Proposal to Suppress the Electronic Case Reporting Measure by Excluding the Measure from Scoring for the MIPS Promoting Interoperability Performance Category for the CY 2025 Performance Period/2027 MIPS Payment Year and the Medicare Promoting Interoperability Program for the EHR Reporting Period in CY 2025

In the proposed rule, CMS notes they have recently been informed by the Centers for Disease Control and Prevention (CDC) that it has temporarily paused electronic case reporting registration and onboarding of new health care organizations (HCOs). Due to this temporary pause, some MIPS eligible clinicians, eligible hospitals, and CAHs may not meet the electronic case reporting registration and onboarding requirements by the end of the CY 2025 performance period and EHR reporting period in CY 2025.

To avoid undue adverse consequences for MIPS eligible clinicians, eligible hospitals, and CAHs as a result of such circumstances, which are outside of their control, CMS proposes to exclude the Electronic Case Reporting measure from scoring under the MIPS Promoting Interoperability performance category for the CY 2025 performance period and the Medicare Promoting Interoperability Program for the EHR reporting period in CY 2025. **The College thanks CMS for coordinating closely with the CDC and other public health agencies to ensure that eligible clinicians, eligible hospitals, and CAHs are not unfairly penalized for circumstances outside their control. The ACC supports the suppression of this measure for the CY 2025 Performance Period/2027 MIPS Payment Year.**

<u>Query of Prescription Drug Monitoring Program (PDMP) Measure RFI</u>

The Query of PDMP measure was initially finalized in the CY 2019 PFS final rule and has subsequently undergone revisions to expand the use of PDMPs as they became more readily available, including modifications in 2023 to include prescribing Schedule II opioids or Schedule III or IV drugs electronically. As CMS notes, PDMPs are now widely available across all 50 States and several localities, and PDMP integration with HIEs, EHRs, and PDSs has increased since the Query of PDMP measure was finalized as an attestation measure.

To further promote the MIPS Promoting Interoperability performance category's capacity to incentivize the electronic exchange of health information using PDMPs and thereby improve the

quality of care by supporting appropriate prescribing of controlled substances, CMS is considering proposing in future rulemaking to expand the Query of PDMP measure to include all Schedule II drugs, rather than only including Schedule II opioids. This would mean the Query of PDMP measure would include all Schedule II (Schedule II opioids and other Schedule II drugs), Schedule III, and Schedule IV drugs.

As CMS considers future rulemaking expanding the Query of PDMP measure, it is important that any expansion only takes place after both state and Certified EHR criteria ensure all eligible clinicians and hospitals can successfully report using CEHRT. This would include finalizing any standards, including the "Prescription Drug Monitoring Program (PDMP) Databases—Query, receive, validate, parse, and filter" certification criterion proposed by ONC in the HTI-2 proposed rule. Currently, a handful of standards utilize for PDMP data collection and reporting, including The Prescription Monitoring Information eXchange National Architecture (PMIX), The National Council for Prescription Drug Programs (NCPDP) standard, HL7 v2, HL7 Admission, Discharge, Transfer (ADT), HL7 Fast Healthcare Interoperability Resources (FHIR), and The American Society for Automation in Pharmacy (ASAP) standard. While many systems are used to using a multitude of standards, the burden for reporting an expanded group of drugs using multiple standards could increase beyond the point and diminish benefits for tracking appropriate prescribing of controlled substances. CMS must balance the potential added costs and burdens placed on eligible clinicians and hospitals before expanding the PDMP measure.

The College also requests CMS consider the potential burden of expanded reporting requirements with an increased number of drugs captured by the Measure. Currently, the PDMP measure is an attestation-based measure with minimal reporting burden. However, CMS is currently exploring changing this to a numerator/denominator-based measure, which coupled with an increase in the number of drugs captured, could substantially increase the reporting burden for eligible clinicians and hospitals. While the ACC is sympathetic to the need to measure and track drug prescriptions of controlled substances, especially those with the potential for patient harm and/or addiction, and has supported development of this measure, the potential increase in burden for reporting could substantially decrease the overall utility of this measure. It is important that CMS continue to balance the need for continued improvements and modifications to the MIPS program with the burdens eligible clinicians and hospitals face when reporting.

Performance-based Measures RFI

Currently, the Medicare PI program requires eligible hospitals and CAHs to report their level of "active engagement," which requires attestation of reporting production data or in the process of validation. CMS notes this does not allow them to assess eligible hospitals and CAHs on the comprehensiveness, quality, or timeliness of the data they provide to PHAs. As CMS examines alternatives to the "active engagement" approach, they seek comments on requiring reporting of measures using numerators/ denominators and adding measures to include additional system-specific requirements.

While the College understands the need to collect more comprehensive data, including quality and timelines of data reported to PHAs, it is important for CMS to consider the scope of data and the difficulties that still exists when reporting to agencies. Without established universal standards for reporting to PHAs, the burden for reporting an unknown number of detailed measures could unfairly burden eligible hospitals and CAHs, overwhelming already overworked and burned-out staff. There are limitations that still exist in using singular data sets to meet all requirement needs, and creating the number of measures needed to meet the needs of PHAs to sufficiently monitor health across the country would erase any progress CMS has made in the "meaningful measures" initiative. It is essential that CMS work to balance the need for specificity with the burden of reporting and need for standardization.

Instead, ONC should work with the CDC, PHAs, and other stakeholders to identify the scope of system-specific measure requirements and determine what would be needed to complete bi-directional clinical data exchange and clearly report these findings. This includes, as will be detailed further below, the creation of a certification program for public health technologies used by PHAs to ensure they have the capabilities required to meet the needs for public health reporting. Outlining these findings and considerations in future rulemaking, such as additional requests for information, would help inform all stakeholders on the scope, benefits, and limitations of an evolving public health reporting program and provide additional informed feedback.

Data Quality RFI

In the proposed rule, CMS seeks comments from stakeholders to encourage and support the use of modern technologies and standards to ensure data are usable, complete, accurate, timely, and consistent. In the request, CMS correctly identifies the risks that come with low-quality data. HHS defines data quality as "the degree to which health information is accurate, complete, timely, consistent, and reliable." As noted, poor data quality poses direct threats to patient safety, especially when providers…treat patients based on inaccurate or incomplete information. CMS also noted "Poor quality data also poses risks beyond health care delivery and administration. Because health care data captured by EHRs serve as the foundation for public health reporting and clinical research using real world evidence, widespread deficits in data quality can adversely affect clinical innovation and public health decision-making".

The College strongly agrees with the sentiment that complete, accurate and timely data is essential to treating patients and encouraging the development of high-quality public health reporting and clinical research, which are essential to clinical innovation and public health decision-making. As such, **the ACC was disappointed to see a recent enforcement discretion memo from the Assistant Secretary for Technology Policy (ASTP)/ Office of the National Coordinator for Health IT (ONC) instructing ONC-Authorized Certification Bodies (ACBs) not to enforce requirements that certified Health IT modules demonstrate the capability to categorize data on individuals based on certain United States Core Data for Interoperability (USCDI) version 3 data elements, including sexual orientation and gender identity.**

As CMS recognizes, complete and accurate data is essential for health care professionals and researchers to make accurate and timely decisions. By exercising this enforcement discretion and allowing certified Health IT vendors to discontinue use of these important data elements, ASTP/ONC risk health care professionals, patients, and researchers having access to incomplete data that could be incredibly important in providing an accurate diagnosis or developing a break-through finding. **While the ACC understands that CMS and ASTP/ONC are bound to follow Executive Order (EO) 14168, "Defending Women from Gender Ideology Extremism and Restoring Biological Truth to the Federal Government," the College asks HHS and ASTP/ONC to consider alternative methods to ensure that data robustness remains a core component of the Health IT certification program.**

Performance Category Scoring, Threshold Stability, and Topped-Out Measures in MIPS

Limited Measure Choice: The ACC appreciates CMS's continued efforts to refine MIPS scoring methodology in ways that better reflect clinicians' actual opportunities to demonstrate meaningful quality improvement. We support the proposal to expand the "limited measure choice" scoring exception to include MVPs, beginning with the 2026 performance year. Given the constrained number of quality measures available within any single MVP, clinicians often encounter high-use measures that are consistently topped out and subject to a scoring cap of 7 points. Applying a capped scoring adjustment in these cases penalizes MVP reporters who are aligning with CMS's preferred reporting framework. Expanding the exemption to MVPs is a fair and logical extension of current policy.

75% Topped Out Threshold: We also support CMS's proposal to maintain the 75% threshold (the rule if ≥ 75% of clinicians score near-perfect (e.g., in the top decile) on a measure or within an MVP set, that measure/set is considered "topped out") for determining whether a measure set or MVP is "at risk" due to topped-out measures. This threshold provides a reasonable benchmark for identifying MVPs and specialty sets where meaningful performance variation is no longer feasible and helps preserve program predictability and fairness. As MVP adoption expands, CMS should monitor for measure sets with high rates of topped out measures and proactively update benchmarks or introduce replacement measures to ensure scoring remains meaningful, particularly for high-volume specialties like cardiology.

75-Point Performance Threshold: More broadly, we support the proposal to maintain a 75-point performance threshold (the final score threshold clinicians must meet or exceed under MIPS to avoid a negative payment adjustment) for the 2028–2030 MIPS payment years. This stability is particularly important given the ongoing transition from traditional MIPS to MVP-based reporting and the phased introduction of digital quality measures (dQMs). Many cardiology practices are still adapting to these changes and will benefit from a predictable scoring environment as MVP infrastructure matures. The College thanks CMS for providing stability in the MIPS program with consistent performance thresholds, allowing eligible clinicians and hospitals to continue to gain experience while preparing for the coming transition towards quality-based care models.

Cardiologists who participate in MVPs like *Advancing Care for Heart Disease* face limited access to specialty-relevant, non-topped-out measures. Without corresponding updates to measure sets, maintaining the same performance threshold or increasing it annually may disproportionately disadvantage clinicians who are already achieving high levels of performance. We recommend CMS pair any future threshold increases with the development of new cardiovascular quality measures and allow greater flexibility in MVP reporting pathways to account for subspecialist variation. In addition, the current structure of the budget neutrality scaling factor often results in negligible rewards even for clinicians with near-perfect scores. For high-performing cardiology groups, this erodes trust in the value of participation and reduces return on investment. The agency may want to consider specialty-adjusted scaling or tiered bonuses to ensure that high-performing clinicians are appropriately rewarded, particularly in specialties like cardiology that frequently report on topped-out measures or are penalized under cost models with limited clinical risk adjustment.

Lastly, we encourage CMS to improve transparency around the scaling factor used to modify positive MIPS payment adjustments. Cardiovascular practices that invest in improving their quality reporting would benefit from better insight into how performance translates into actual payment adjustments. This clarity would support more informed business planning, resource allocation, and technology upgrades.

Scoring Administrative Claims-Based Measures (CY2025 Performance Period/2027 MIPS Payment Year)

We appreciate CMS's proposal to revise the methodology for scoring administrative claims-based quality measures within the MIPS Quality Performance Category beginning with the CY 2025 performance period/2027 MIPS payment year. The current decile-based benchmarking methodology may underrepresent the performance of clinicians whose outcomes cluster near the median, particularly for inverse outcome measures such as unplanned cardiovascular-related hospital admissions. Using a method based on standard deviation, the median, and scoring linked to the MIPS performance threshold would make the evaluation of claims-based measures more fair, consistent, and statistically sound.

Specifically, tying scores to the median helps ensure that clinicians who perform at an average level are not unfairly penalized. Using benchmarks from the same performance period also makes sense for claims-based measures, since clinicians do not have to submit data themselves. Given that estimates show that average scores would likely rise (from around 5.6 to 7.0 out of 10), this approach better reflects how most clinicians are performing, without giving an unfair boost to top outliers. Moreover, the duplication of changes to mirror the Cost category would bring welcome consistency.

The College urges CMS to monitor for any unintended effects, like reduced score variability or less distinction between high and low performers and readjust if needed. This method should be used for all current and future claims-based quality measures to ensure consistency, as well as all categories of measures. Finally, we request CMS be transparent about how benchmark ranges and standard deviations are set each year and share expected performance thresholds in advance.

Future MIPS Performance Thresholds RFI

In the proposed rule, CMS seeks comments on establishing the performance threshold for single versus multiple years (for example, 1, 2, or 3 years at a time) via rulemaking as well as increasing the performance threshold based on data from a prior period which potentially would provide larger positive MIPS payment adjustments for MIPS eligible clinicians with MIPS final scores higher than such performance threshold. **As CMS considers these potential changes, it is essential that any modifications to performance thresholds are communicated with sufficient notice of proposed rulemaking, allowing eligible clinicians and hospitals time to prepare.**

When establishing performance thresholds, it is important to ensure that these thresholds are not only established well ahead of time but also are based on data that accurately reflects true eligible clinician and hospital reporting over time. Basing future thresholds on a single previous year, including potential increases in adjustments, it may not reflect current or future reporting requirements. Every year, there are a number of factors that change, which can impact reporting abilities. These range from external macro factors to adjustments in measures available for reporting. While CMS has afforded exceptions to reporting to adjust for adverse circumstances, other factors can still impact reporting. **Accordingly, selecting future thresholds from multiple years provides a more accurate representation of historical reporting abilities. The College believes this will better reflect reporting abilities and give eligible clinicians and hospitals an increased chance of achieving MIPS final scores higher than the established performance threshold.**

Advanced APMs

The College appreciates CMS's efforts to modernize QP determinations and broaden participation in Advanced APMs. We support the proposal to add individual-level QP determinations beginning in 2026, as this approach better recognizes the contribution of clinicians who meaningfully engage in Advanced APMs but may be disadvantaged if their APM Entity fails to meet thresholds. We encourage CMS to provide clear guidance on how services furnished across multiple TINs will be assessed for a single NPI and to minimize administrative burden associated with tracking QP status at both the entity and individual level. In addition, attribution rules must be carefully designed to ensure that specialists, such as cardiologists practicing in multispecialty groups, are not penalized despite actively managing high-risk patients. Expanding attribution from just E/M visits to all services may make it harder for specialists to qualify as QPs. CMS should test the impact by specialty, like cardiology, and adjust attribution so it reflects who actually manages patients over time.

The ACC also supports CMS's proposal to align the QP Targeted Review process with MIPS but recommend extending the review period beyond 15 days. Attribution lists and participation files for specialty clinicians are frequently inaccurate or incomplete, and adequate time is needed to identify and correct errors. CMS should also improve transparency by making available the underlying claims and attribution data used in QP determinations.

Advancing Care for Heart Disease MVP

We appreciate CMS's effort to refine the Advancing Care for Heart Disease MVP and recommend evolving it to a hybrid, modular structure. CMS could construct a small, cross-cutting core (a few universal measures/activities) and add selectable subspecialty modules: e.g., Electrophysiology, Interventional/Structural, Heart Failure, Imaging, and General Cardiology. This would allow groups or subgroups to choose the module(s) that match their actual work, with CMS using recent claims/diagnoses to suggest a module and clinicians able to confirm or switch. This preserves the MVP promise of lower burden and better fit while maintaining comparability through a consistent core set. We encourage the addition of more measures to make participation easier for clinicians.

This change aligns measurement with how cardiology is typically organized, which is by subspecialty/service line rather than single disease "silos". This also acknowledges that many cardiology teams do not "own" primary-care tasks (like vaccines). Mandatory assignment from procedural codes alone risks misclassification, higher burden, and disengagement. A modular design improves relevance without sacrificing program integrity.

In practice, the core set would include a small number of cross-cutting quality items, one improvement activity, and applicable Promoting Interoperability elements. Subspecialty modules would then focus on measures that reflect the work in that area. For example, EP (safety such as tamponade/device infection, plus rhythm-control/anticoagulation outcomes and post-procedure follow-up); Interventional/Structural (access-site bleeding, AKI, readmission, and evidence-based medications); Heart Failure (ARNI/ACE/ARB, beta-blocker, MRA, SGLT2 inhibitor; and timely follow-up, paired with the HF cost measure and clear attribution rules); Imaging (right imaging for the right patient, based on diagnosis and where they're treated); and General Cardiology/CAD (outcome-oriented lipid control such as LDL-C <70 or risk-based LDL reduction, plus secondary prevention).

For attribution and assignment, CMS could use the past 1–2 years of claims, and then combine procedures with diagnoses, E/M visit patterns, and place of service to suggest a module. Clinicians would then validate or change the suggestion to reflect current scope of practice, similar to the ASM concept of claims-based suggestion with clinician confirmation. To keep results fair and comparable, we recommend eligibility guardrails: minimum volume and minimum share of practice in the chosen domain (for example, ≥20–25 cases and ≥20–30% of E/M visits or allowed charges in that domain). Each module could include an outcome measure, with topped-out process measures used only as complements. CMS should recognize emerging fields like cardio-oncology and cardio-obstetrics, which have few distinctive CPT codes. These can be identified through diagnosis/E/M patterns, and clinicians should be allowed to select the best-fit module when codes are insufficient.

For the proposed MVP, the ACC offers the following comments:

Topped-out Process Measures: Many of the included quality measures, such as Q005, Q006, Q007, and Q008, are longstanding process measures that have become topped out (MIPS CQMs) or exhibit

limited performance variation. Their inclusion should be paired with balancing outcome measures, such as measures focused on cardiovascular event rates or evidence-based medication adherence (e.g., statin therapy for secondary prevention).

Heart Failure Group: This clinical grouping includes both a robust set of quality measures and a corresponding cost measure (COST_HF_1), which may create concerns about double-counting performance on related services. If clinicians provide more care to meet heart failure quality targets, like prescribing the right medications or ordering follow-ups, costs will subsequently increase. There is then the risk of being penalized by the cost measure, even though clinicians are following guidelines and doing the right thing for patients. We request that CMS provide clarity on how attribution and scoring will be managed to avoid overlapping penalties or confusion for clinicians. Likewise, while we appreciate the inclusion of relevant cost measures across groupings, attribution still may pose a problem, particularly for clinicians whose care may only partially contribute to a given episode.

Electrophysiology Group: The EP grouping appears underdeveloped. While measures Q392 and Q393 reflect important safety concerns (e.g., pericardial complications and device infections), there is no measure of success or adherence in rhythm control, nor attention to post-procedural follow-up or anticoagulation outcomes. CMS should consider whether additional outcome or functional measures could be incorporated into this grouping to better reflect the full spectrum of EP care. For atrial fibrillation ablation, CMS could consider allowing appropriateness measures as an alternative reporting option to PROMs.

General Cardiology: The CAD grouping lacks a meaningful outcome measure and relies heavily on older process-based measures. Key aspects of modern CAD management, such as statin therapy for secondary prevention and the use of SGLT2 inhibitors in appropriate patients, are absent. To improve clinical relevance and drive meaningful improvement, CMS should include or develop a true outcome measure for CAD, such as cardiovascular event rates, and re-evaluate the measure set to reflect current, high-impact treatment strategies. Additional potential measures could include referral to and participation in cardiac rehabilitation following PCI, as well as the use of PROMs for patients with stable CAD.

Health and Wellness: The inclusion of general preventive and wellness measures, such as Q047 (Advance Care Planning), Q134 (Depression Screening), and Q238 (High-Risk Medications in Older Adults), raises additional questions. While these are clinically valuable and relevant across multiple specialties, their placement in a cardiology-focused MVPs are questionable since they have the potential to create attribution challenges in multispecialty practices. We recommend that CMS consider reserving such measures for broader MVPs or ensure they are optional within this MVP.

Proposed Removal of Q487: Screening for Social Drivers of Health: We encourage CMS to retain Q487 within the MVP. Addressing SDOH is vital to equitable and effective cardiovascular care. Cardiovascular risk factors, such as medication adherence, diet, transportation, and housing insecurity, are often closely tied to unaddressed SDOH, which in turn adversely affect outcomes like blood pressure control and heart failure readmissions.

Participation and Scoring Issues: Based on the 2023PY public use file data for MIPS and the MVPs, only 48 clinicians (38 CV specialists) received a final score from the Heart Disease MVP out of 731 registrants. The average overall score under the MVP was just 32.67, compared to 85.87 under traditional MIPS, a 53-point gap that suggests issues such as design flaws or usability issues. CMS should review the specifications, attribution methodology, and data submission requirements for this MVP to ensure feasibility and fairness, particularly for cardiology subspecialties.

Cost vs. Quality Scores: Also based on the 2023PY public use file data, clinicians in the MVP scored very well on cost (mean: 83.34), but low on quality (mean: 51.18), suggesting the quality measures may not align well with practice patterns or EHR data capture. CMS should revise the quality component to better reflect contemporary cardiovascular care and streamline reporting mechanisms to reduce barriers.

Advancing Care for Heart Disease MVP: Gaps in Measures

While we appreciate CMS's efforts to align the MVP with cardiology, key gaps remain. These include the lack of measures for hypertension, peripheral artery disease (frequent overlap with HF and CAD), valvular heart disease (e.g., TAVR, MitraClip), and cardiomyopathies. The MVP includes older process measures (ACEI/ARB/ARNI, beta blocker use) but omits newer therapies like SGLT2 inhibitors for HF and CAD, GLP-1 agonists for ASCVD risk reduction in diabetics, and statin use.

As described, most measures are either process-based or unstratified outcome/safety measures. As a result, CMS might miss the opportunity to encourage improvement in high-risk subgroups. PROMS or meaningful outcome or functional measures for conditions like atrial fibrillation (e.g., post-ablation AF burden) and coronary artery disease (e.g., stable angina) would be welcome. Similarly, measures for electrophysiology focus on complications and not on therapeutic success (arrhythmia recurrence or hospital avoidance), symptom improvement, or adherence (e.g., to DOACs).

If feasible for both CMS and clinicians, parsimonious composites and outcomes could be utilized in place of individual measures. In addition, data that is already available, as well as the use of CDS/registries to minimize manual work, would advance relevance without adding to clinician or facility burden.

Conclusion

Thank you for your consideration of these comments and the Agency's efforts on behalf of Medicare beneficiaries. The ACC stands ready to be a resource as you continue this work. Please contact Matthew Minnella, Associate Director of Medicare Payment Policy, at mminnella@acc.org should any additional information be needed.

Sincerely,

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